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(71) Applicant: ONUX MEDICAL, INC. [US/US]; 5 Merrill Drive, Hampton, NH 03842 (US).

(72) Inventors: SANCOFF, Gregory, E.; 120 Mill Road, North Hampton, NH 03862 (US). FIELD, Frederic, P.; 5 Woodland Road, North Hampton, NH 03862 (US). FOGG, Douglas, A.; 15 South Pleasant Street, Merrimac, MA 01860 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

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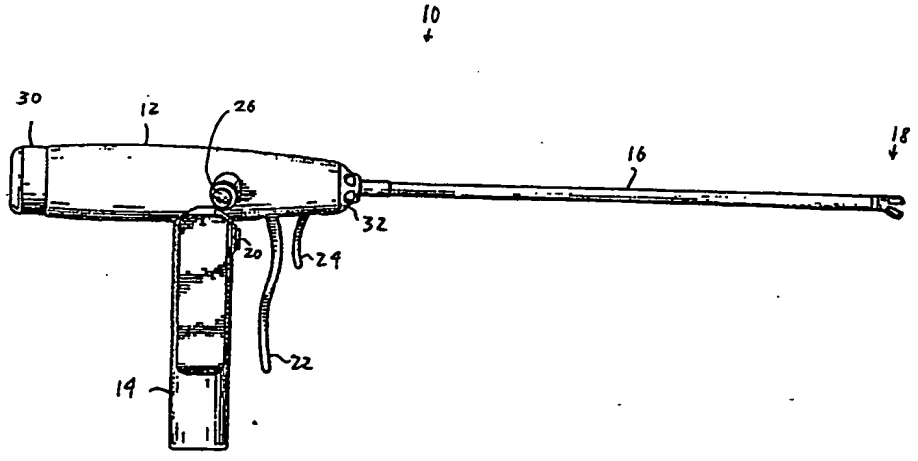

(57) Abstract

A device (10) comprises a handle (14), a flexible elongated element (58), and two jaw portions (96, 98). The device (10) further includes a proximal end (30), a distal end (18), an advancement unit (72) for advancing the flexible elongated member (58) toward the distal end (18), and a securing unit (28) for variably adjusting a securing force applied by the flexible elongated element (58).

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SURGICAL SUTURING INSTRUMENT AND METHOD OF USE

Reference To Earlier Applications

The present application claims the benefit of pending prior U.S. Provisional Patent Application Serial No. 60/098,152, filed August 27, 1998 by Gregory E. Sancoff et al. for MEDICAL SUTURE INSTRUMENT, and pending prior U.S. Provisional Patent Application Serial No. 60/118,039, filed February 1, 1999 by Gregory E. Sancoff et al. for ENDOSCOPIC WIRE SUTURING DEVICE.

The two above-identified documents are hereby incorporated herein by reference.

Field Of The Invention

This invention relates to medical instruments and procedures in general, and more particularly to suturing instruments and methods for suturing.

Background Of The Invention

Suturing instruments are typically used to draw together two or more portions of a subject patient (e.g., tissue such as muscle or skin) or to attach an

object to the patient (e.g., to attach a piece of surgical mesh to the abdominal wall of the patient during hernia repair surgery).

Certain suturing instruments employ a needle that precedes a length of suture material through a subject.

For example, U.S. Patents Nos. 3,470,875; 4,027,608; 4,747,358; 5,308,353; 5,674,230; 5,690,653; 5,759,188; and 5,766,186 generally disclose suturing instruments in which a needle, with trailing suture material, is passed through a subject.

U.S. Patents Nos. 4,890,615; 4,935,027; 5,417,700; and 5,728,112 generally disclose suturing instruments in which suture material is passed through the end of a hollow needle after that needle has passed through a subject.

With all of the foregoing devices, a needle must be passed through the subject in order to deploy the suture. This is generally undesirable, since the needle typically leaves a larger hole in the subject than is necessary to accommodate only the suture material. In this respect it should be appreciated that it is generally desirable to alter each portion of the material being sutured as little as possible.

A suturing instrument has been devised which permits the suture material itself to pierce the subject without the use of a needle. However, this device does not permit sufficient flexibility with regard to the amount of tension that may be applied to the suture and tissue.

More particularly, U.S. Patent No. 5,499,990 discloses a suturing instrument in which a 0.25 mm stainless steel suturing wire is advanced to the distal end of a suturing instrument, whereupon the distal end of the suturing wire is caused to travel in a spiral direction so as to effect stitches joining together two portions of a subject. After the spiral is formed, the beginning and end portions of the suture may be bent toward the tissue in order to inhibit retraction of the suture wire into the tissue upon removal of the suturing instrument. The stainless steel wire is sufficiently firm to hold this locking set. In addition, after the spiral is formed, the radius of the deployed suture spiral may then be decreased by advancing an outer tube over a portion of the distal end of the instrument. Again, the stainless steel wire is sufficiently firm to hold this reducing set.

Unfortunately, however, such a system does not permit sufficient flexibility in all situations with regard to the appropriate amount of tension to be applied to the subject, since the wire is relatively firm (i.e., firm enough to hold its sets). Such a system also does not provide sufficient flexibility with regard to the appropriate type of suture stitch to be applied, since the device is specifically configured to provide only a spiral suture stitch.

In contrast to the aforementioned limitations of the suturing instrument of U.S. Patent No. 5,499,990, it is desirable that a suturing instrument approximate the portions of the material which is to be joined in the correct physiological relationship, and to urge the portions together with an appropriate amount of force. If too much force (or tension) is applied to the suture material, then the subject portions may become necrotic or the sutures may cut through the subject. If too little tension is applied to the suture material, then the healing process may be impaired.

U.S. Patent No. 4,453,661 discloses a surgical instrument for applying staples. The staples are formed from the distal end of a length of wire. The

distal end of the wire is passed through a subject, and thereafter contacts a die that causes the wire to bend, thereby forming the staple. The wire is sufficiently firm to take the set imposed by the die. The staple portion is then cut from the wire by a knife. Again, such a system suffers from the fact that it does not permit sufficient flexibility in all situations with regard to the appropriate tension to be applied to the subject, since the attachment is made by a staple which has a predefined geometry and is formed with relatively firm wire. In addition, the system is limited as to the type of fastening which may be applied, since the surgical instrument is limited to only applying wire staples.

There is a need, therefore, for a new suturing device that permits minimally disruptive suturing and permits flexibility in the placement, application, and tensioning of the suture material.

Summary Of The Invention

The invention provides a device for introducing a flexible elongated element through a subject. In one embodiment, the device includes a proximal end and a

distal end, as well as an advancement unit for longitudinally advancing the flexible elongated element toward the distal end of the device such that a distal end of the flexible elongated element may pass from the distal end of the device with sufficient force to pass through the subject. The device also includes a securing unit for variably adjusting a securing force applied by the flexible elongated element so as to provide the desired securement to the subject.

In further embodiments, the device includes a guide tube for guiding the flexible elongated element through the device, toward the distal end of the device, as well as a rotation unit for rotating the distal end of the device so as to cause the flexible elongated element to wrap around itself, whereby to adjustably apply the securing force to the flexible elongated element.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiment of the invention, which is

to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

Fig. 1 is a side view of a suturing instrument formed in accordance with the present invention;

Fig. 2 is a partial side view, partially in section, of the suturing instrument shown in Fig. 1;

Fig. 3 is a partial top view, partially in section, of the suturing instrument shown in Fig. 1;

Fig. 4 is a schematic partial side view showing some of the internal components of the suturing instrument shown in Fig. 1;

Fig. 4A is a perspective view of a drive barrel assembly incorporated in the suturing instrument shown in Fig. 1;

Fig. 5 is a perspective view of a wire guide support unit incorporated in the suturing instrument shown in Fig. 1;

Fig. 6 is a perspective view of the suturing instrument's wire supply cartridge, which includes the wire guide support unit shown in Fig. 5;

Fig. 7 is a perspective view, partially in section, of the wire supply cartridge shown in Fig. 6;

Fig. 8 is a perspective rear view of the drive barrel assembly incorporated in the suturing instrument shown in Fig. 1, with the drive barrel assembly's release lever being shown in its closed position;

Fig. 9 is a perspective view of the proximal (i.e., rear) end of the drive barrel assembly shown in Fig. 8, with the release lever being shown in its open position;

Fig. 10 is a perspective view of the proximal (i.e., rear) end of the same drive barrel assembly, with the release lever being shown in its closed position, and with the wire guide and wire guide support unit being advanced relative to the drive barrel assembly (but with the remainder of the wire supply cartridge being removed from view);

Fig. 11 is a schematic view taken along the line 11-11 of Fig. 4;

Fig. 12 is a side view of a shaft and an end effector portion of the suturing instrument shown in Fig. 1;

Fig. 13 is a side view of the end effector portion of the suturing instrument shown in Fig. 1;

Fig. 14 is a side view, partially in section, of the end effector portion shown in Fig. 13, with the end effector portion being shown with its cutting bar in its forward (i.e., non-cutting) position;

Fig. 15 is a side view, partially in section, of the end effector portion shown in Fig. 14, but with the end effector portion being shown with its cutting bar in its retracted (i.e., cutting) position;

Fig. 16 is a perspective view of the end effector portion of the suturing instrument shown in Fig. 1;

Figs. 17A - 17J show various steps in a suturing operation conducted with the suturing instrument shown in Fig. 1;

Fig. 18 is a sectional view showing one possible construction for the suturing instrument's fixed jaw portion and its associated cutting bar;

Fig. 19 is a side view showing a piece of wire cut with the apparatus shown in Fig. 18;

Fig. 20 is a sectional view showing another possible fixed construction for the suturing instrument's fixed jaw portion and its associated cutting bar;

Fig. 21 is a side view showing a piece of wire cut with the apparatus shown in Fig. 20;

Fig. 22 is a side view, partially in section, of the end effector portion of the device, wherein the end effector portion includes a piezoelectric element to aid in wire penetration;

Fig. 23A is a schematic diagram of the device's fixed jaw portion, illustrating how the suture wire may sometimes curve as it exits the fixed jaw portion;

Fig. 23B is a schematic diagram of a modified form of the device's fixed jaw portion, illustrating how the profile of the device can be modified so as to counteract the aforementioned wire curvature;

Fig. 23C is a schematic diagram of a modified form of the device's movable jaw portion, illustrating how the mouth of the movable jaw portion's opening may be enlarged so as to facilitate suture capture;

Fig. 24 is a schematic diagram of a modified form of the device, wherein one or more legs have been provided to help stabilize the tissue during suturing; and

Fig. 25 is a schematic diagram of another modified form of the device, wherein a second set of jaws have

been added to the device to help stabilize the tissue during suturing.

Detailed Description Of The Preferred Embodiment

Overview

Looking first at Fig. 1, there is shown a suturing instrument 10 which comprises a preferred embodiment of the present invention. Suturing instrument 10 includes a housing 12, a handle 14, a shaft 16 and an end effector 18. Suturing instrument 10 also includes a wire advance button 20, a jaw closing actuator 22, a wire cutting actuator 24, a left-thumb-actuated rotation button 26, and a right-thumb-actuated rotation button 28 (Fig. 3). Suturing instrument 10 also includes a wire supply cartridge 30, as well as a shaft retaining nut 32. Shaft retaining nut 32 allows shaft 16 to be dismounted from the remainder of the device for cleaning purposes.

As will be discussed in further detail below, generally during use, suture wire (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) is drawn from a

winding in wire supply cartridge 30 and is pushed through housing 12 and shaft 16 to end effector 18, which includes a pair of opposing jaw portions. The jaw portions may be brought together around the material which is to be sutured by actuating jaw closing actuator 22 when the jaw portions are positioned at an appropriate surgical location. The suture wire is driven through housing 12 and shaft 16 to end effector 18 by actuating wire advance button 20. The suture wire is driven from one jaw portion to the other jaw portion with sufficient force to penetrate the tissue placed between the jaw portions, and the suture wire is permitted to pass through the second jaw portion. The jaw portions are then permitted to separate and move away from the tissue, leaving the suture wire extending from the subject tissue to each of the two jaw portions. Shaft 16 and end effector 18 (together with wire supply cartridge 30) may then be rotated with respect to housing 12 and handle 14 by actuating either left-thumb-actuated rotation button 26 or right-thumb-actuated rotation button 28. This causes the portions of the suture wire that extend from

the tissue to be twisted about one another so as to form a closed loop extending through the tissue. It will be appreciated that the size of this closed loop may be adjustably reduced by increasing the degree of twisting in the wire. The twisted loop of suture wire may then be cut off, at end effector 18, from the remaining portion of the suture wire that extends back through the suturing instrument. Such cutting may be effected by actuating wire cutting actuator 24.

As will be discussed in further detail below, wire supply cartridge 30 may be supplied separately from suturing instrument 10, with the wire supply cartridge 30 being loaded into suturing instrument 10 prior to commencing a suturing operation. As will also be discussed in further detail below, wire supply cartridge 30 may be disposable, such that the cartridge may be discarded after all of its wire has been used up.

Construction Details

As shown in Figs. 2 and 4, handle 14 provides a cavity that may receive batteries 34. In other embodiments, the unit may be powered remotely via a power transmission cord or any other source of suitable power.

Batteries 34 supply a ground (or negative) potential to a ground connector post 36 (Fig. 2), which in turn communicates with a rotary ground communicator 38. Rotary ground communicator 38 permits electrical contact to be maintained with ground connector post 36 when rotary ground communicator 38 is rotated with respect to ground connector post 36, as occurs when shaft 16 and end effector 18 are rotated so as to twist closed suture wire extending through the tissue.

Batteries 34 supply a positive potential to wire advance button 20, and to a first connector post 40, which in turn communicates with a first rotary electrical communicator 42. First rotary electrical communicator 42 permits electrical contact to be maintained with first connector post 40 when first rotary electrical communicator 42 is rotated with

respect to first connector post 40. The positive potential from batteries 34 is also supplied (in parallel) to each thumb-activated rotation button 26, 28 (Fig. 3), and to a second connector post 44 (Fig. 2), which in turn communicates with a second rotary electrical communicator 46. Again, second rotary electrical communicator 46 permits electrical contact to be maintained with second connector post 44 when second rotary electrical communicator 46 is rotated with respect to second connector post 44. Each of the connector posts 36, 40 and 44 may be spring-biased so as to remain in contact with its respective rotary communicator. In view of the foregoing construction, the positive potentials may be switched on by depressing the respective actuator button 20, 26, 28. Handle 14 also includes a cap 48 which may be removed so as to permit insertion of batteries 34.

First rotary electrical communicator 42 is in electrical communication with a wire advance motor 50 shown in Figs. 2 and 4. The output shaft of wire advance motor 50 is coupled to a miter drive gear 52, which is in turn coupled to a miter follower gear 54. Miter follower gear 54 is coupled to a drive wheel 56

which contacts the suture wire 58, as will be described in further detail below with reference to Figs. 5-10.

Second rotary electrical communicator 46 is in electrical communication with a shaft rotation motor 60 (Figs. 3 and 4), the output of which is coupled to a pinion gear 62 (Figs. 4, 4A and 11) that rotates along an internal gear 64 (Figs. 4 and 11). As shown in Fig. 3, left-thumb-actuated rotation button 26 and right-thumb-activated rotation button 28 may be provided to permit the user to use the thumb of either their left hand or their right hand, respectively, so as to actuate shaft rotation motor 60. In this respect it will be appreciated that, inasmuch as left-thumb-actuated rotation button 26 and right-thumb-actuated rotation button 28 are wired in parallel, shaft rotation motor 60 will rotate in the same direction regardless of which button (i.e., button 26 or button 28) may be actuated.

Jaw closing actuator 22 (Figs. 2 and 4) is coupled to a jaw linkage coupler 66, which in turn contacts a jaw linkage 68 (Figs. 2 and 14). When jaw closing actuator 22 is pulled toward handle 14 (Fig. 2), jaw closing actuator 22 pivots on its pivot pin 67 (Fig. 4)

so as to drive jaw linkage coupler 66 distally, against the force of biasing spring 69, and so as to cause the jaw linkage 68 to move forward toward the distal end of suturing instrument 10. This action will in turn cause movable jaw portion 98 to close on fixed jaw portion 96 (Fig. 17A), as will hereinafter be discussed in further detail. When jaw closing actuator 22 is subsequently released, biasing spring 69 (Fig. 4) drives jaw linkage coupler 66 proximally, so as to cause jaw linkage 68 to move proximally. This action will cause movable jaw portion 98 to open relative to fixed jaw portion 96 (Fig. 14), as will hereinafter be discussed in further detail. The action of jaw linkage 68 at the distal end of the device is discussed further below with reference to Figs. 13 and 14.

Wire cutting actuator 24 is coupled to a wire cutting linkage coupler 70 (Figs. 2 and 4), which in turn contacts a wire cutting linkage 72 (Figs. 2, 14 and 15). When wire cutting actuator 24 is pulled toward handle 14 (Fig. 2), wire cutting actuator 24 pivots on its pivot pin 73 (Fig. 4) so as to drive wire cutting linkage coupler 70 proximally, against the force of biasing spring 69, and so as to cause wire

cutting linkage 72 to move proximally, away from the distal end of suturing instrument 10. This action will in turn cause cutting bar 104 (Fig. 14) to move proximally (Fig. 15) so as to effect wire cutting, as will hereinafter be discussed in further detail. When wire cutting actuator 24 is subsequently released, biasing spring 69 drives wire cutting linkage coupler 70 distally, so as to cause wire cutting linkage 72 to move distally. This action causes cutting bar 104 to move distally, so as to assume the position shown in Fig. 14. Wire cutting linkage 72 moves adjacent to, and independent of, jaw linkage 68 discussed above. The action of wire cutting linkage 72 at the distal end of the device is discussed further below with reference to Figs. 14 and 15.

The wire supply cartridge 30 shown in Fig. 1 includes a wire guide support unit 74, as shown in Figs. 5-7. A supply coil of suture wire 58 (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) may be supplied in the base of cartridge 30 and is fed into the support unit 74 as shown in Fig. 7. A wire guide 76 surrounds suture wire 58, from support unit 74 to

the distal end of suturing instrument 10, adjacent to end effector 18 (Figs. 5-7, 14 and 15). Wire guide 76 ensures that suture wire 58 does not bend or buckle as the suture wire is pushed through housing 12 and shaft 16. More particularly, wire guide 76 preferably forms a sufficiently close sliding fit with suture wire 58 such that suture wire 58 cannot bend or buckle as the suture wire is advanced through suturing instrument 10. At the same time, wire guide 76 is also formed so as to present a minimum of friction to suture wire 58 as the suture wire is advanced through the instrument. The foregoing characteristics are important, inasmuch as suture wire 58 is extremely thin and flexible and highly susceptible to bending or buckling in the absence of some sort of lateral support.

By way of example but not limitation, where suture wire 58 is formed out of stainless steel and has a diameter of 0.005 inch, wire guide 76 might have an inside diameter of 0.008 inch and an outside diameter of 0.016 inch. In addition, wire guide 76 is preferably formed out of polytetrafluoroethylene (PTFE) or some other relatively lubricious material.

Alternatively, the interior of wire guide 76 may be coated with a lubricant so as to facilitate closely-supported, low-friction passage of the suture wire through the wire guide.

Further by way of example but not limitation, in one preferred form of the invention, suture wire 58 may comprise 316 LVM stainless steel having a tensile strength of 170 kpsi.

Although wire guide 76 extends through support unit 74 (Fig. 7), wire guide 76 has two openings 78 (one on either side of wire guide 76, only one of which is shown in Fig. 5) in the center of support unit 74. Openings 78 expose a portion of suture wire 58 so that wire drive wheel 56 (Fig. 8) may contact suture wire 58 and urge the suture wire forward toward the distal end of suturing instrument 10, as will be discussed in detail below with reference to Figs. 8-10.

As shown in Figs. 2, 3, 4A and 8, housing 12 receives a drive barrel assembly 80 that contains the aforementioned motors 50 and 60, and provides a distally-extending barrel shaft 81 (Figs. 4A and 8), on the outside of which are located the rotary communicators 38, 42 and 46'. A recess 82 (Fig. 4A) is

provided on the distal end of barrel shaft 81 for receiving a coupling pin 84 (Figs. 2 and 4) which is located on the proximal end of shaft 16, such that rotation of drive barrel assembly 80 causes rotation of coupling pin 84 and hence shaft 16. Drive barrel assembly 80 is rotationally held within housing 12 by bearings 86, as shown in Figs. 2 and 3.

Looking next at Figs. 7-10, wire supply cartridge 30 may be attached to drive barrel assembly 80 by rotating a release lever 87 away from the center of drive barrel assembly 80 (Figs. 8 and 9), so as to move a carriage 88 relative to drive barrel assembly 80. Most particularly, release lever 87 rides on a pin 90, and rotation of release lever 87 from the position shown in Fig. 8 to the position shown in Fig. 9 draws carriage 88, as well as a wire follower wheel 92, away from the center of drive barrel assembly 80. Once wire follower wheel 92 is separated from wire drive wheel 56 by a sufficient distance to expose the drive barrel assembly's central passageway 93 (Fig. 9), wire guide 76 (overlying suture wire 58) may be inserted into passageway 93 (Fig. 10), and wire guide support unit 74 (Figs. 6, 7 and 10) may be inserted between wheels 56

and 92 (Fig. 10), such that wheels 56 and 92 contact either side of suture wire 58 through openings 78 formed in either side of wire guide 76. A biasing spring 94 (Figs. 8-10) is provided on carriage 88 to urge wire follower wheel 92 into close contact with suture wire 58. In other embodiments, wire follower wheel 92 may also be driven indirectly by wire drive wheel 56 in order to provide additional forces to move suture wire 58 distally (i.e., forward, toward the tool's end effector 18).

Pinion gear 62 (Figs. 4, 4A and 11) extends distally from drive barrel assembly 80 and engages the housing's internal gear 64, as shown in Figs. 4 and 11. As a result of this construction, when shaft rotation motor 60 is actuated, pinion gear 62 rotates around internal gear 64, bringing with it the entire drive barrel assembly 80. This in turn causes shaft 16 to rotate, since shaft 16 is coupled to drive barrel assembly 80. More particularly, the rotation of drive barrel assembly 80 is transferred to shaft 16 through the shaft's coupling pin 84 (Figs. 2, 4 and 12), which is seated in recess 82 (Fig. 8) of drive barrel assembly 80.

End effector 18 (Figs. 1 and 13-16) includes a fixed jaw portion 96 and a movable jaw portion 98. Movable jaw portion 98 is coupled to the aforementioned jaw linkage 68 (Fig. 14) via a jaw linkage pin 100, such that when jaw linkage 68 is moved distally (i.e., by pulling jaw closing actuator 22 toward handle 14), jaw portion 98 is rotated about a pivot pin 102 (Fig. 13) and closes onto fixed jaw portion 96. Conversely, when jaw linkage 68 is moved proximally (i.e., by the power of biasing spring 69 acting on jaw linkage coupler 66 and hence jaw linkage 68), movable jaw portion 98 will open away from fixed jaw portion 96. It will be appreciated that the force of biasing spring 69 will normally keep movable jaw portion 98 open relative fixed jaw portion 98 (Figs. 1, 13 and 14), unless and until jaw closing actuator 22 is activated so as to overcome the bias of spring 69.

Wire cutting linkage 72 (Figs. 2, 3, 14 and 15) is coupled to a cutting bar 104 (Figs. 14 and 15) that includes a small opening 106 through which suture wire 58 may pass, as will hereinafter be discussed in further detail. Preferably cutting bar 104 is slidably received in a passageway 107 (Figs. 14, 15, 16 and 17H)

formed in fixed jaw portion 96. In one position (Fig. 14), cutting bar 104 is positioned in fixed jaw portion 96 such that the cutting bar's opening 106 is aligned with a channel 108 formed in fixed jaw portion 96, whereby suture wire may be passed from the distal end of wire guide 76, through channel 108 formed in fixed jaw portion 96 (where it undergoes an approximately 90 degree change of direction), through opening 106 in cutting bar 104, through a channel extension 108A formed in fixed jaw portion 96, and across to movable jaw portion 98, as will hereinafter be discussed in further detail. However, when wire cutting linkage 72 is moved proximally by pulling wire cutting actuator 24 toward handle 14, cutting bar 104 is also moved proximally (Fig. 15) so as to cut any suture wire extending from channel 108 (in fixed portion 96) into opening 106 (in cutting bar 104). In this respect it will be appreciated that it is desirable to form channel extension 108A with a length greater than channel 108 (see Figs. 14 and 15) so as to prevent the suture wire from being cut in two places (i.e., at channel 108 and again at channel extension 108A) when

cutting bar 104 is moved proximally by pulling on wire cutting actuator 24. At the same time, however, it should also be appreciated that the fixed jaw portion's channel 108 and channel extension 108A, and the cutting bar's opening 106, are all sized, relative to suture wire 58, so as to provide as much support as possible to the suture wire as it passes through, and out of, fixed jaw portion 96.

It will be appreciated that the force of biasing spring 69 will normally keep cutting bar 104 in its distal position (i.e., with the cutting bar's opening 106 aligned with the fixed jaw portion's channel 108), unless and until wire cutting actuator 24 is activated so as to overcome the bias of spring 69.

In view of the foregoing construction, it will be seen that: (1) release lever 87 (Figs. 8-10) may be activated so as to move wire follower wheel 92 away from, and toward, wire drive wheel 56 so as to permit a full wire supply cartridge 30 (Figs. 1 and 5-7) to be loaded into suturing instrument 10; (2) activating jaw closing actuator 22 will cause movable jaw portion 98 to close on fixed jaw portion 96; (3) activating wire advance button 20 will cause wire drive wheel 56 to

advance suture wire 58 through housing 12 and shaft 16; (4) activating rotation button 26 and/or rotation button 28 will cause shaft 16 to rotate relative to housing 12; and (5) activating wire cutting actuator 24 will cause cutting bar 104 to move proximally so as to sever any suture wire extending from fixed jaw portion 96.

Operation

Suturing instrument 10 may be used to apply wire suture 58 to a subject so as to effect a desired suturing operation.

By way of example but not limitation, and looking now at Figs. 17A-17J, suturing instrument 10 may be used to suture together two portions 110, 112 of a subject which is to be sutured. In a typical case, portions 110, 112 might comprise two sections of severed tissue which need to be reattached to one another, or two pieces of previously unattached tissue which need to be attached to one another. However, one or the other of the portions 110, 112 might also comprise artificial mesh or some other object being attached to tissue, etc. In addition, in a typical

case, portions 110, 112 might be located relatively deep within a patient, and might be accessed during a so-called "minimally invasive", or a so-called "closed surgery", procedure; however, in other circumstances, portions 110, 112 might be accessed during a conventional, or so-called "open surgery", procedure. This later situation might include procedures done at the outer surface of the patient's body, i.e., where portions 110, 112 comprise surface subjects.

In any case, suturing instrument 10 is initially prepared for use by installing batteries 34 into handle 14, if batteries 34 are not already installed, and by installing wire supply cartridge 30 into the suturing instrument, if a cartridge 30 is not yet installed. As noted above, wire supply cartridge 30 is installed in suturing instrument 10 by (1) moving the drive barrel assembly's release lever 87 to its open position (Fig. 9), so as to move wire follower wheel 92 away from wire drive wheel 56 and thereby expose the barrel assembly's central passageway 93; (2) passing the distal end of the cartridge (i.e., the distal end of wire guide 76) through drive barrel assembly 80 and shaft 16 until the distal end of wire guide 76 is in communication with

the channel 108 formed in fixed jaw portion 96 (Fig. 14), at which point the cartridge's wire guide support unit 74 will be positioned intermediate wire drive wheel 56 and wire follower wheel 92 (Fig. 2); and (3) moving the drive barrel assembly's release lever 87 back to its closed position (Fig. 8), so as to cause wire drive wheel 56 and wire follower wheel 92 to extend through the wire guide's openings 78 and engage suture wire 58.

At this point suturing instrument 10 will be ready for use, with its movable jaw portion 98 being opened away from its fixed jaw portion 96, and with its cutting bar 104 being in its forward (Fig. 14) position.

Next, suturing instrument 10 has its movable jaw portion 98 moved into engagement with its fixed jaw portion 96 (i.e., the jaws 96, 98 are placed in their "closed" position) by pulling jaw closing actuator 22 toward handle 14, and then the distal end of suturing instrument 10 is moved adjacent to subject portions 110, 112 (Fig. 17A).

In the case of a so-called closed surgical procedure, such positioning will generally involve

moving the distal end of the suturing instrument through a cannula and into an interior body cavity; however, it is also envisioned that one might move the distal end of the suturing instrument directly into an otherwise-accessible body cavity, e.g., directly into the colon or esophagus, etc. In the case of a so-called open surgical procedure, such positioning might involve positioning the distal end of the suturing instrument adjacent to more readily accessible subject portions 110, 112.

In any case, once the distal end of suturing instrument 10 has been placed adjacent to subject portions 110, 112, jaw closing actuator 22 is released, such that biasing spring 69 (Fig. 4) will cause movable jaw portion 98 to open away from fixed jaw portion 96 (Fig. 17B). Then the distal end of suturing instrument 10 is moved so that its jaws 96, 98 straddle subject portions 110, 112, and then jaw closing actuator 22 is actuated again, by pulling jaw closing actuator 22 toward handle 14, so as to close movable jaw portion 98 against fixed jaw portion 96, whereby to capture subject portions 110, 112 (Fig. 17C).

Next, wire advance button 20 is activated so as to cause suture wire 58 to be driven forward, out of the distal end of wire guide 76, through the fixed jaw portion's channel 108, through opening 106 in cutting bar 104, through the fixed jaw portion's channel extension 108A, through subject portions 110, 112, and finally through an opening 113 (Figs. 14, 15 and 17C) formed in movable jaw portion 98. Suture wire 58 is preferably advanced so that a length 58A of wire 58 extends approximately 1 centimeter out of the bottom end of movable jaw portion 98 (Fig. 17C). In this respect it will be appreciated that, as suture wire 58 leaves fixed jaw portion 96 and engages subject portions 110, 112, the fixed jaw portion's channel 108, the cutting bar's opening 106 and the fixed jaw portion's channel extension 108A will support the thin suture wire so as to enable the suture wire to penetrate subject portions 110, 112.

Once this has been done, jaw closing actuator 22 is released so as to permit movable jaw portion 98 to return to its "open" position relative to fixed jaw portion 96, and then wire advance button 20 is used to pay out additional suture wire 58 as the distal end of

suturing instrument 10 is stepped back (e.g., by about a centimeter or so) from subject portions 110, 112 (Fig. 17D).

Then jaw closing actuator 22 is used to move jaw portion 98 back into engagement with fixed jaw portion 96 once more (Fig. 17E).

Next, left-thumb-actuated rotation button 26, or right-thumb-actuated rotation button 28, is used to rotate shaft 16 and hence end effector 18. This causes suture wire 58 to twist on itself, initially creating a relatively large loop 116 (Fig. 17F) of suture wire 58 extending from subject portions 110, 112 toward suturing instrument 10. However, as rotation button 26 and/or rotation button 28 is used to rotate shaft 16 (and hence end effector 18) more and more, the loop 116 of suture material will progressively close down (Fig. 17G) so as to form a tight binder for subject portions 110, 112. In this respect it will be appreciated that the longer the period of time that end effector 18 is rotated, the greater the amount of twisting of suture wire 58, and the greater the force holding subject portions 110, 112. In this respect it will also be appreciated that suture wire 58 is preferably carefully

selected with respect to its flexibility relative to the strength of subject portions 110, 112. In particular, suture wire 58 is chosen so as to have a flexibility such that the suture wire will twist, and loop 116 will close down, before subject portions 110, 112 will undergo substantial deformation and/or tearing. By way of example but not limitation, in practice, it has been found that 0.005 inch diameter stainless steel wire can be used with most types of mammalian tissue such that the suture wire can be twisted closed without causing substantial deformation and/or tearing of the tissue.

Once suture wire 58 has been tightened to the desired degree, rotation of shaft 16 and end effector 18 is stopped, i.e., by releasing button 26 or button 28. Then wire cutting actuator 24 is depressed (e.g., it is pulled back toward handle 14) so as to pull cutting bar 104 proximally and thereby sever the suture wire 58 as the suture wire emerges from the fixed jaw portion's channel 108 and enters the cutting bar's opening 106 (Fig. 17H and Fig. 16). This action separates the deployed suture wire extending through subject portions 110, 112 from the suture wire

remaining in wire supply cartridge 30, wire guide 76 and the fixed jaw portion's channel 108.

Then wire cutting actuator 24 is released, allowing biasing spring 69 to return cutting bar 104 to return to its distal position, and then jaw closing actuator 22 is released, allowing movable jaw portion 98 to move away from fixed jaw portion 96. Suturing instrument 10 may then be removed from subject portions 110, 112, which action will pull wire length 58A from movable jaw portion 98 (Fig. 17I).

The deployed suture wire 58 may then be pressed down flat against subject portions 110, 112, or rounded into a ball, or otherwise operated upon, so as to reduce the profile of, or reduce the tendency to snag on, the deployed suture wire (Fig. 17J).

It will be appreciated that suturing instrument 10 will have application in a broad range of different suturing operations. More particularly, it will be appreciated that suturing instrument 10 will have application in both "open" and "closed" surgical procedures, with the former including, but not limited to, large entry procedures, relatively shallow procedures, and surface procedures; and with the latter

including, but not limited to, surgical procedures where access is gained to an interior structure through the use of a cannula, and surgical procedures where access is gained directly to an internal body cavity without the use of a cannula, e.g., such as a procedure conducted within the colon or the esophagus.

It will also be appreciated that suturing instrument 10 will have application where two portions of tissue must be attached to one another (e.g., where two severed pieces of tissue must be re-attached to one another, or where two separate pieces of tissue must be attached to one another, or where two sections of a single piece of tissue must be approximated to one another), and where an object must be attached to the patient (e.g., where surgical mesh must be attached to the patient's abdominal wall during hernia repair surgery, etc.).

Among other things, it is believed that suturing instrument 10 will have particular application in the areas of general laparoscopic surgery, general thoracic surgery, cardiac surgery, general intestinal surgery, vascular surgery, skin surgery and plastic surgery.

Looking next at Figs. 18 and 19, it will be seen that where the fixed jaw portion's channel 108 is disposed so as to be substantially aligned with the center of cutting bar 104 (Fig. 18), suture wire 58 will be cut with a relatively flat leading end 58B (Fig. 19). However, it has sometimes been found helpful to provide suture wire 58 with a relatively sharp leading point. Such a leading point can help open the subject for the following portion of the suture wire. In addition, such a leading point can help the suture wire penetrate the subject with a substantially straight path, so that the suture wire will reliably enter the movable jaw portion's opening 113. To this end, it has been found that moving the fixed jaw portion's channel 108 off-center relative to cutting bar 104 (Fig. 20) will cause the leading end 58B of suture wire 58 to be formed with a relatively sharp tip 58C (Fig. 21).

It is also possible to use suturing instrument 10 to ligate a subject rather than to pass a suture through the subject. For example, suturing instrument 10 might be used to ligate a blood vessel with suture wire 58. In this case, suturing instrument 10 is

deployed so that suture wire 58 will pass around the far side of the subject, rather than through the subject as in the case of the suturing operation of the type described above.

By way of example but not limitation, in a typical ligating operation, movable jaw portion 98 is first opened relative to fixed jaw portion 96. Then suturing instrument 10 is positioned about the subject so that when movable jaw portion 98 is thereafter closed toward fixed jaw portion 96, the fixed jaw portion's channel 108 and the movable jaw portion's opening 113 will both lie on the far side of the subject. The movable jaw portion 98 is then closed against the fixed jaw portion 96, and suture wire 58 is passed from fixed jaw portion 96 to movable jaw portion 98, i.e., around the far side of the subject. The movable jaw portion 98 is then opened, and suture wire 58 is payed out as the instrument is stepped back from the subject. Then the movable jaw portion 98 is again closed against the fixed jaw portion 96. The shaft of the instrument is then rotated so as to form, and then close down, the ligating loop. Then cutting bar 104 is activated so as to cut the ligating loop from the remainder of the

suture wire still in the tool, the movable jaw member 98 is opened, and the instrument is withdrawn from the surgical site. The deployed suture wire 58 may then be pressed down flat against the subject, or rounded into a ball, or otherwise operated upon, so as to reduce the profile of, or reduce the tendency to snag on, the deployed suture wire. As will be appreciated by a person skilled in the art, where instrument 10 is to be used for ligating purposes, fixed jaw portion 96 and movable jaw portion 98 might be formed with a greater longitudinal length so as to facilitate passing the suture wire around the far side of the subject. Furthermore, movable jaw member 98 might be formed with a recess, intermediate its jaw linkage pin 100 (Fig. 15) and its opening 113, for accommodating the subject, whereby to prevent compressing the subject when movable jaw member 98 is moved into engagement with fixed jaw member 96.

Suture wire 58 may comprise a wire formed out of a metal or any other suitable material having the required flexibility and stiffness. By way of example but not limitation, suture wire 58 may comprise stainless steel, titanium, tantalum, etc.

If desired, suture wire 58 may also be coated with various active agents. For example, suture wire 58 may be coated with an anti-inflammatory agent, or an anti-coagulant agent, or an antibiotic, or a radioactive agent, etc.

Looking next at Fig. 22, it is also possible to impart ultrasound energy to the wire in order to make tissue penetration easier. More particularly, because of the small cross-sectional area of the wire and the propensity for the wire to buckle when axially loaded, it is beneficial to be able to advance the wire into tissue with a minimum of load. This can be achieved by appropriately applying ultrasound energey to the wire.

A piezoelectric element 200 is placed at the outside radius of the wire guide path 108 at the right angle bend in the fixed jaw portion 96 just before where the wire enters the tissue. The piezoelectric element 200 vibrates at a position along this bend such that it supports the wire in completing the turn but also imparts a component of displacement in the direction of the tissue. Displacement of this kind at ultrasonic frequencies, in addition to the existing wire driving means, would cause the tip of the wire to

penetrate the tissue using less force. In addition to reducing the tendency for outright wire buckling, lowering the wire loads will also allow the wire penetration to proceed in a straighter path.

Looking next at Fig. 23A, it will be seen that, in some circumstances, the suture wire 58 may exit fixed jaw portion 96 with a curvature, due to the fact that suture wire 58 follows a curved channel 108 in fixed jaw portion 96. In some cases this curvature in the suture wire 58 may be quite modest, so that it may be effectively ignored. However, in other circumstances, this curvature might be large enough to cause the suture wire advancing out of fixed jaw portion 96 to miss the target opening 113 in movable jaw portion 98. In this case the curvature in suture wire 58 can present a significant problem. However, and looking now at Fig. 23B, it has been found that the profile of the cutting bar's opening 106 may be modified so as to provide a deflecting die which will counteract undesirable curvature in the suture wire and return the suture wire to a straight path as the suture wire exits fixed jaw portion 96. Alternatively, the profile of the fixed jaw portion's channel 108 may be modified,

adjacent to cutting bar 104, so as to provide a similar deflecting die which will counteract undesirable curvature in the suture wire and return the suture wire to a straight path as the suture wire exits fixed jaw portion 96. Futhermore, and looking now at Fig. 23C, the mouth of the movable jaw portion's opening 113 may be enlarged to help capture a suture wire deviating from a straight path.

Looking next at Fig. 24, it will be seen that one ore more legs 300 may be provided on suturing instrument 10, wherein legs 300 help stabilize the tissue during suturing.

And looking next at Fig. 25, it will be seen that a grasper 400, comprising jaws 405 and 410, may be added to suturing instrument 10 to help stabilize the tissue during suturing.

If desired, the end effector 18 of suturing instrument 10 may be constructed so as to have two movable, opposing jaws, rather than one fixed jaw and one movable jaw as described above.

Also, if desired, shaft rotation motor 60 and thumb buttons 26, 28 may be configured so that depressing one button (e.g., button 26) will cause end

effector 18 to rotate in one direction (e.g., clockwise), and depressing the other button (e.g., button 28) will cause end effector 18 to rotate in the opposite direction (e.g., counterclockwise).

Modifications

It will be appreciated by those skilled in the art that numerous modifications and variations may be made to the above-disclosed embodiments without departing from the spirit and scope of the present invention.

What Is Claimed Is:

1. A device for fixing a flexible elongated element to a portion of a subject, said device comprising:

structure for retaining the flexible elongated element;

advancement means for longitudinally advancing the flexible elongated element from a proximal end of said device toward a distal end of said device with sufficient force to pass the element through the portion of the subject; and

securing means for securing the element to the subject and for variably adjusting a securing force applied by the flexible elongated element to the portion of the subject.

2. The device as claimed in claim 1, wherein a longitudinal axis extends between said proximal and distal ends of said device, and wherein said securing means include a rotation unit for rotating said distal end of said device about said longitudinal axis.

3. The device as claimed in claim 1, wherein said distal end of said device includes at least one adjustable jaw for gripping the portion of the subject between opposing jaw surfaces.

4. The device as claimed in claim 1, wherein said advancement means include at least one drive wheel for contacting said flexible elongated element, and guide means for permitting said flexible elongated element to move only in a direction corresponding to a longitudinal axis of said flexible elongated element.

5. The device as claimed in claim 1, wherein said device further includes a cutting unit for selectively cutting a portion of a distal end of said flexible elongated element.

6. A device for use in passing a flexible elongated element through at least two portions of a subject, said device comprising:

a hollow wire guide for guiding the flexible elongated element through said device toward a distal end of said device and toward the subject;

at least one drive unit for urging the elongated element toward said distal end of said device through said hollow wire guide, and passing the elongated element through the at least two portions of the subject; and

securing means for variably adjusting a securing force applied by the flexible elongated element to the at least two portions of the subject, so as to secure together the at least two portions of the subject with a selected force.

7. The device as claimed in claim 6, wherein said device further includes a longitudinal axis extending between a proximal end and said distal end of said device, and wherein said securing means include a rotation unit for rotating said distal end of said device about said longitudinal axis.

8. The device as claimed in claim 6, wherein said distal end of said device includes at least one

adjustable jaw for gripping the at least two portions of the subject between opposing jaw surfaces.

9. The device as claimed in claim 6, wherein said advancement means include at least one drive wheel for contacting said flexible elongated element, and further wherein said hollow wire guide is adapted to permit said flexible elongated element to move only in a direction corresponding to a longitudinal axis of said flexible elongated element.

10. The device as claimed in claim 6, wherein said device further includes a cutting unit for selectively cutting a portion of a distal end of said flexible elongated element.

11. Apparatus for joining two segments at a surgical site, said apparatus comprising:

a flexible elongated element including a first portion and a second portion;

means for advancing said first portion of said flexible elongated element through each of a first segment and a second segment; and

means for joining said first portion of said flexible elongated element with said second portion of said flexible elongated element such that the joinder is variably adjustable, whereby each of said first and second segments are maintained in selected proximity to one another.

12. Apparatus as claimed in claim 11, wherein said flexible elongated element further includes a third portion, and said apparatus further includes means for cutting said flexible elongated element at a location between said second and third portions of said flexible elongated element.

13. A system for providing controlled movement of a flexible elongated element within a medical instrument, said system comprising:

support means mounted in the medical instrument for axially surrounding the flexible elongated element, said support means including at least one opening; and

drive means mounted in the medical instrument for contacting the flexible elongated element through said opening so as to urge said flexible elongated element

to move longitudinally within said support means, said support means serving to inhibit lateral movement of said flexible elongated element.

14. A system as claimed in claim 13, wherein said system further includes rotation means for rotating a distal end of said device.

15. A suturing instrument for joining portions of a subject during a medical procedure, said device comprising:

a proximal end, a distal end, and a longitudinal axis extending between said proximal and distal ends, said distal end including an opening;

a flexible elongated element extending along said longitudinal axis toward said distal end;

guide means for restricting the movement of said flexible elongated element in directions other than along said longitudinal axis; and

advancement means for advancing said flexible elongated element along said longitudinal axis toward said distal end of said device.

16. A method of applying sutures with a suturing instrument, said method comprising the steps of:

advancing a suture material along a longitudinal axis of the suturing instrument toward a distal end thereof;

forcing the suture material through a subject to be sutured at the distal end of the suturing instrument;

twisting together a free end of the suture material extending from the subject and a remaining portion of the suture material so as to lock the free end of the suture material to the remaining portion of the suture material.

17. The method as claimed in claim 16, wherein said method further includes the step of severing the twisted suture material from the suture material within the suturing instrument.

18. A device for fixing a wire in tissue, the device comprising:

support structure for retaining the wire;

advancement apparatus for advancing the wire through said support structure and out a distal end portion of said support structure with sufficient force to drive a distal end portion of the wire through the tissue;

receiving structure for receiving and retaining the distal end portion of the wire; and

rotation apparatus for twisting together the distal end portion of the wire and a further portion of the wire adjacent to the distal end portion of the wire, so as to adjustably fix the wire to the tissue.

19. A device according to claim 18 further comprising a severing device for severing the further portion of the wire from a remainder of the wire.

20. A device according to claim 18 further comprising control structure on said device for selectively determining the degree of twisting of said distal end portion of the wire and said further portion of the wire.

21. A device for fixing a wire in tissue, the device comprising:

support structure for retaining the wire;

opposed gripper members at a distal end of said device for gripping the tissue therebetween;

advancement apparatus for advancing the wire through said support structure and out a distal portion of a first of said gripper members with sufficient force to drive a distal end portion of the wire through the tissue and into a receiving cavity in a distal end portion of a second of said grippers; and

rotation apparatus for rotating said gripper members about an axis for twisting together said distal end portion of the wire and a further portion of the wire adjacent the distal end portion of the wire, so as to adjustably fix the wire to the tissue.

22. An assembly for suturing together first and second portions of tissue, the assembly comprising:

a wire suture element, said wire suture element being of such flexibility as to (1) bend if not supported along a length thereof, and (2) twist upon

itself and not deform tissue in which said wire suture element is disposed;

support structure for retaining said wire suture element along a selected path;

opposed gripper members fixed to a distal end of said support structure for gripping the tissue portions therebetween, said gripper members having opposed channels therein for receiving said wire suture element, said channels being generally normal to a lengthwise axis of said support structure;

advancement apparatus for advancing the wire suture element through said support structure, through the channel in a first of said gripper members, through the tissue portions, and into the channel in a second of said gripper members; and

rotation apparatus for rotating said gripper members around the lengthwise axis of said support structure for twisting together first and second portions of the wire suture element adjacent to the tissue, whereby to variably join together the two wire suture element portions and thereby suture together the first and second portions of tissue.

23. An assembly according to claim 22 further comprising a handle proximate a proximal end of said assembly, and wherein said support structure comprises an elongated tube extending between said handle and said gripper members, such that said gripper members are sufficiently spaced from said handle to facilitate disposition and operation of said gripper members within a mammalian body while said handle is disposed outside of said mammalian body, for control of said gripper members and said wire suture element from outside of said mammalian body.

24. A suture supply cartridge for a suture tool, the tool comprising a housing, an elongated tube extending from the housing, an advancement apparatus for advancing a suture distally through the tube, and a control actuator mounted on the housing for selective operation of the suture advancement apparatus, the suture supply cartridge comprising:

a cartridge housing adapted for attachment to the tool;

a wall disposed in said cartridge housing and, in cooperation with said cartridge housing, defining a chamber for storage of the suture;

a wire guide support having a base portion fixed to said wall, and having a protrusion portion extending distally from said base portion, said base portion and said protrusion portion defining a bore extending axially therethrough, said protrusion portion having openings in side walls thereof; and

an elongated suture guide fixed in said wire guide support and extending distally therefrom, said suture guide having openings in side walls thereof aligned with said protrusion openings, the suture extending through said suture guide;

said suture wire guide protrusion openings being adapted to receive drive wheel portions of the tool advancement apparatus upon connection of said cartridge housing to said tool, such that said drive wheel portions extend through said suture guide openings to engage the suture.

25. A method for suturing first and second tissue portions, the method comprising:

holding an edge of the first tissue portion adjacent to an edge of the second tissue portion;

driving a strand of suture material through the first and second tissue portions proximate to the tissue portion edges, a portion of the strand exiting the second tissue portion;

twisting together the exited portion of the strand and a portion of the strand adjacent to a suture entry location on the first tissue portion; and

severing the suture to separate the twisted-together portions of the strand from a remainder of the suture strand.

26. A method according to claim 25, further comprising an initial step of selecting the strand of suture material exhibiting such flexibility as to (1) bend if not supported along a length thereof, and (2) twist upon itself and not deform the tissue into which it is driven.

27. A method according to claim 25 wherein the degree of twisting of the twisted-together portions of the strand is selected so as to provide a selected

tightness of a resulting strand loop extending through the tissue portions.

28. A method according to claim 25 including the step of providing a tool for effecting the method, the tool having a handle portion proximate a proximal portion of the tool and a distal end portion removed from the handle portion by a distance sufficient to enable disposition and operation of the distal end portion of the tool within a mammalian body while the handle portion remains disposed outside of mammalian body, the method further including the steps of inserting the distal end portion of the tool in the mammalian body, locating the distal end portion adjacent to a site for suturing, and operating mechanisms on the handle portion outside of the mammalian body to effect suturing inside the mammalian body.

29. A system for suturing tissue at a surgical site within a mammalian body, the system comprising:

a single instrument for passing a first portion of suture through the tissue and for intertwining the

first portion of suture with a second portion of suture so as to form a joinder of said suture portions at the surgical site, whereby to lock the suture in position relative to the tissue.

30. A system according to claim 29 wherein said single instrument further comprises cutting apparatus for severing said second suture portion from a remaining portion of suture.

31. A suturing device, comprising:

a housing;

a shaft extending distally from said housing;

a pair of opposing jaws located at a distal end of the shaft, said jaws adapted to grasp two elements to be sutured together without piercing the elements; and

a source of suture material located in the housing, the distal end of the suture material extending through the shaft and being adapted to be pushed through the two elements to be sutured together.

32. A suturing device, comprising:

a housing;

a shaft extending distally from said housing;

a pair of opposing jaws located at a distal end of the shaft;

a source of suture material located in the housing; and

a motor located in the housing for rotating the shaft and the jaws about an axis.

33. A suturing device, comprising:

a housing;

a shaft extending distally from said housing;

a pair of opposing jaws located at a distal end of the shaft;

a source of suture material located in the housing;

a first motor located in the housing for advancing the suture material through the shaft, through one of the jaws, through two elements to be sutured together, and into the other jaw; and

a second motor located in the housing for rotating the shaft and the jaws to secure the suture material to the two elements.

34. The device of claim 33, wherein the suture material comprises a wire.

35. The device of claim 33, further comprising a handle attached to said housing.

36. The device of claim 33, wherein the source of suture material comprises a wire supply cartridge having a length of wire wound thereon.

37. The device of claim 33, further comprising an actuator for opening and closing the jaws.

38. A method for suturing together two separate elements, comprising:

bringing the first element adjacent the second element;

piercing the first and second elements with a length of suture material through the first and second elements, such that a free, distal portion of the suture material extends distally past the second

element and a proximal portion of the suture material extends proximally past the first element; and

twisting together the free distal portion and the proximal portion of the suture material to secure the first and second elements together.

39. The method of claim 38, further comprising severing the twisted portion of the suture material from the remaining suture material.

40. Apparatus for ligating a subject at a surgical site, said apparatus comprising:

a flexible elongated element including a first portion and a second portion;

means for advancing said first portion of said flexible elongated element around the subject; and

means for joining said first portion of said flexible elongated element with said second portion of said flexible elongated element such that the joinder is variably adjustable.

41. Apparatus according to claim 11 wherein said first and second segments comprise two portions of the same structure.

42. Apparatus according to claim 11 wherein said first and second segments comprise two portions of two different structures.

43. The method as claimed in claim 16, wherein said method further comprises the step of operating on the twisted-together free end and remaining portion so as to reduce the tendency to snag on the same.

44. The method as claimed in claim 43 wherein said step of operating on comprises pressing down flat the twisted-together free end of remaining portion.

45. The method as claimed in claim 43 wherein said step of operating on comprises forming a ball with the twisted-together free end and remaining portion.

46. The device as claimed in claim 6 wherein a lubricious material is positioned between said flexible elongated element and said hollow wire guide.

47. The device as claimed in claim 5 wherein said cutting unit is adapted to cut said flexible elongated element so as to form a sharp point on said flexible elongated element.

48. Apparatus as claimed in claim 11, wherein said flexible elongated element is coated with an agent selected from the group consisting of anti-inflammatory agents, anti-coagulant agents, antibiotics, and radioactive agents.

49. Apparatus as claimed in claim 11, wherein said flexible elongated element is formed out of metal.

50. Apparatus as claimed in claim 49, wherein said metal comprises at least one of the group consisting of stainless steel, titanium and tantalum.

51. Apparatus according to claim 11 wherein said means for advancing includes a piezoelectric element.

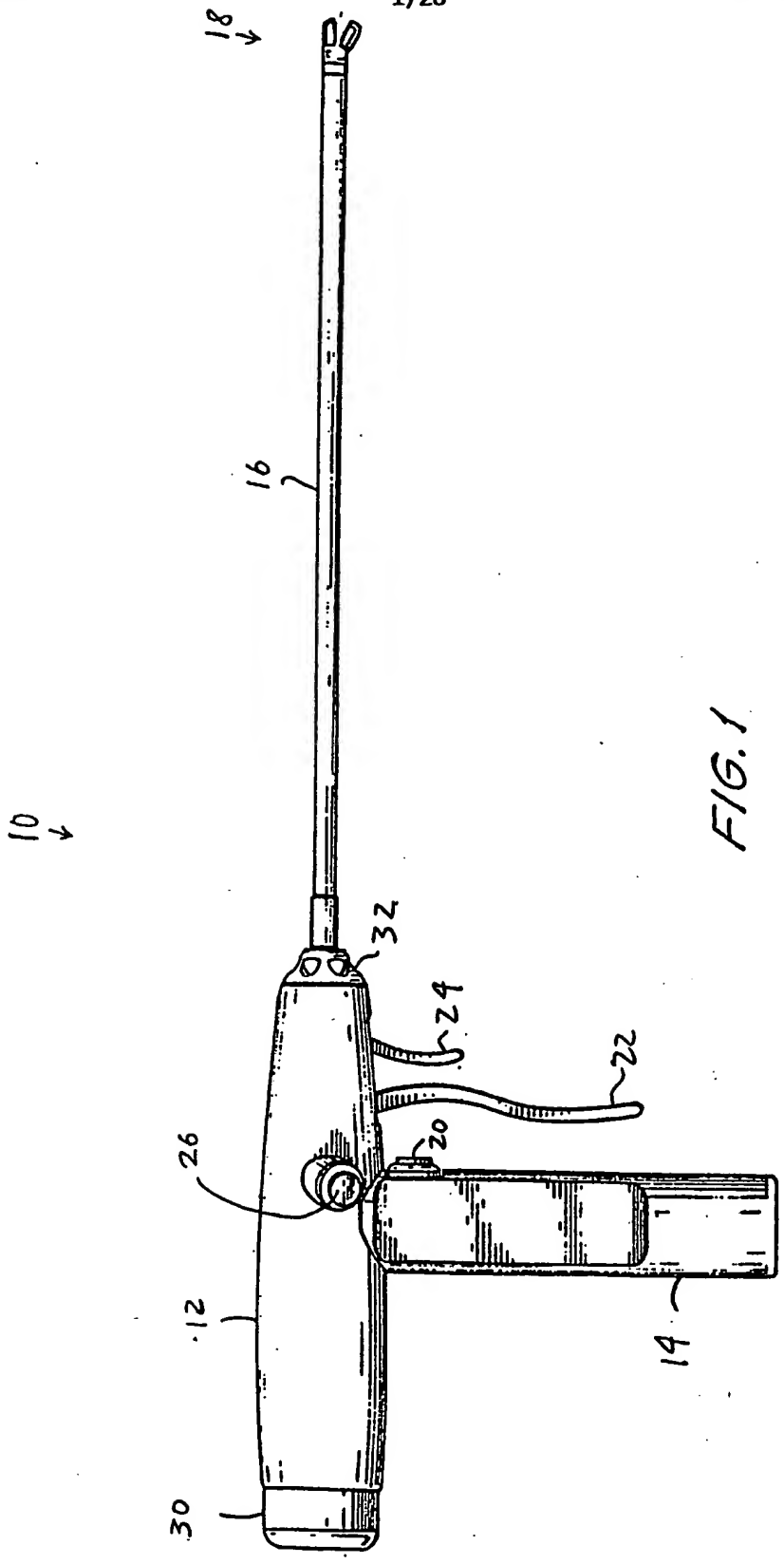

FIG. 1

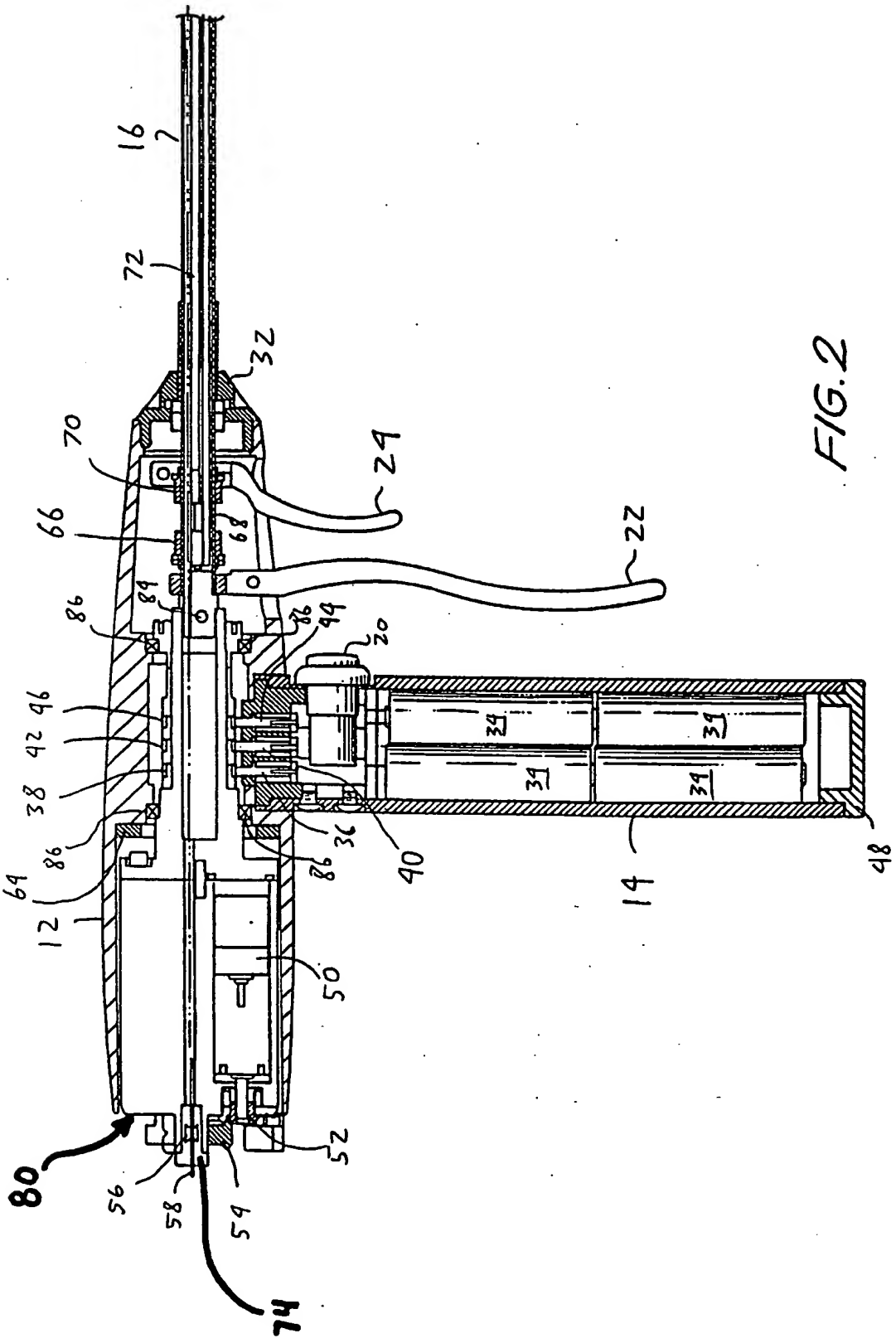
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FIG. 2

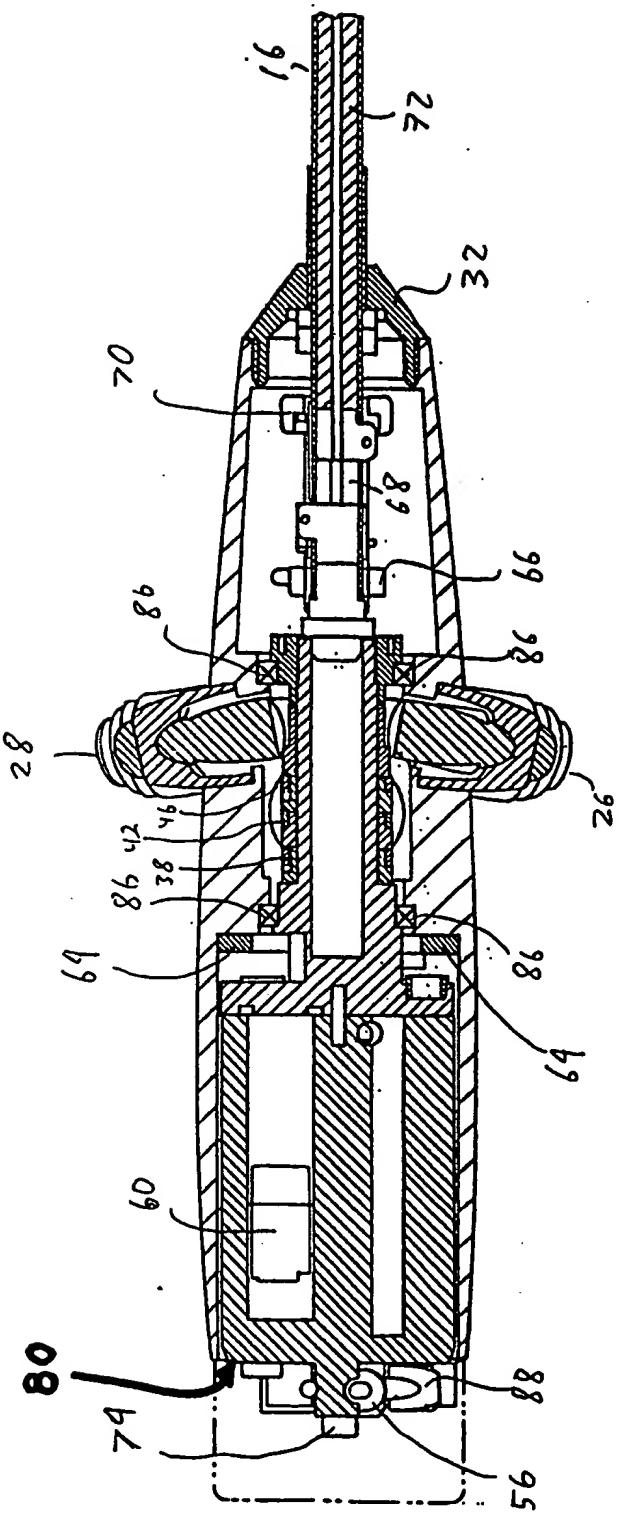

FIG. 3

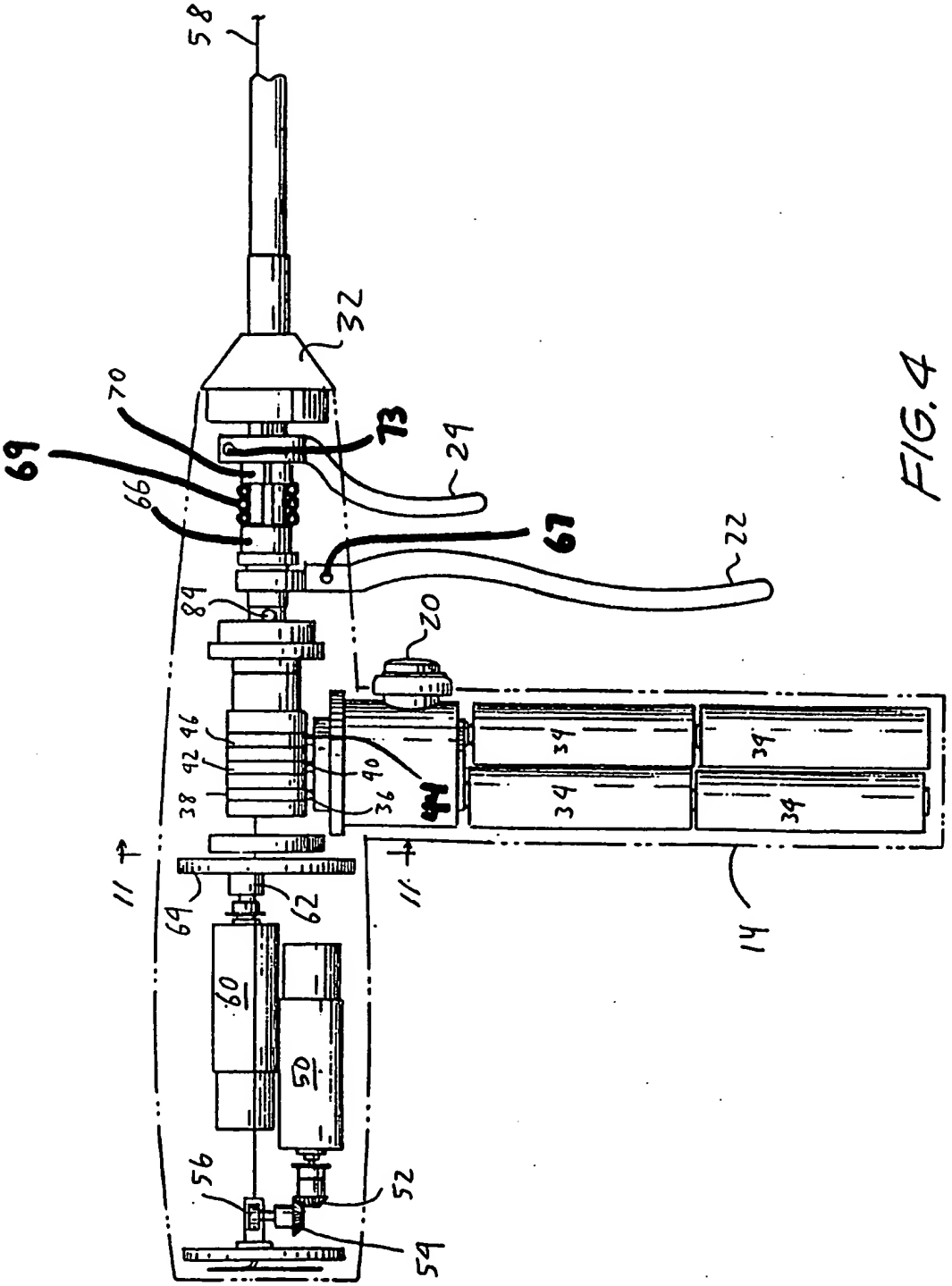
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FIG. 4

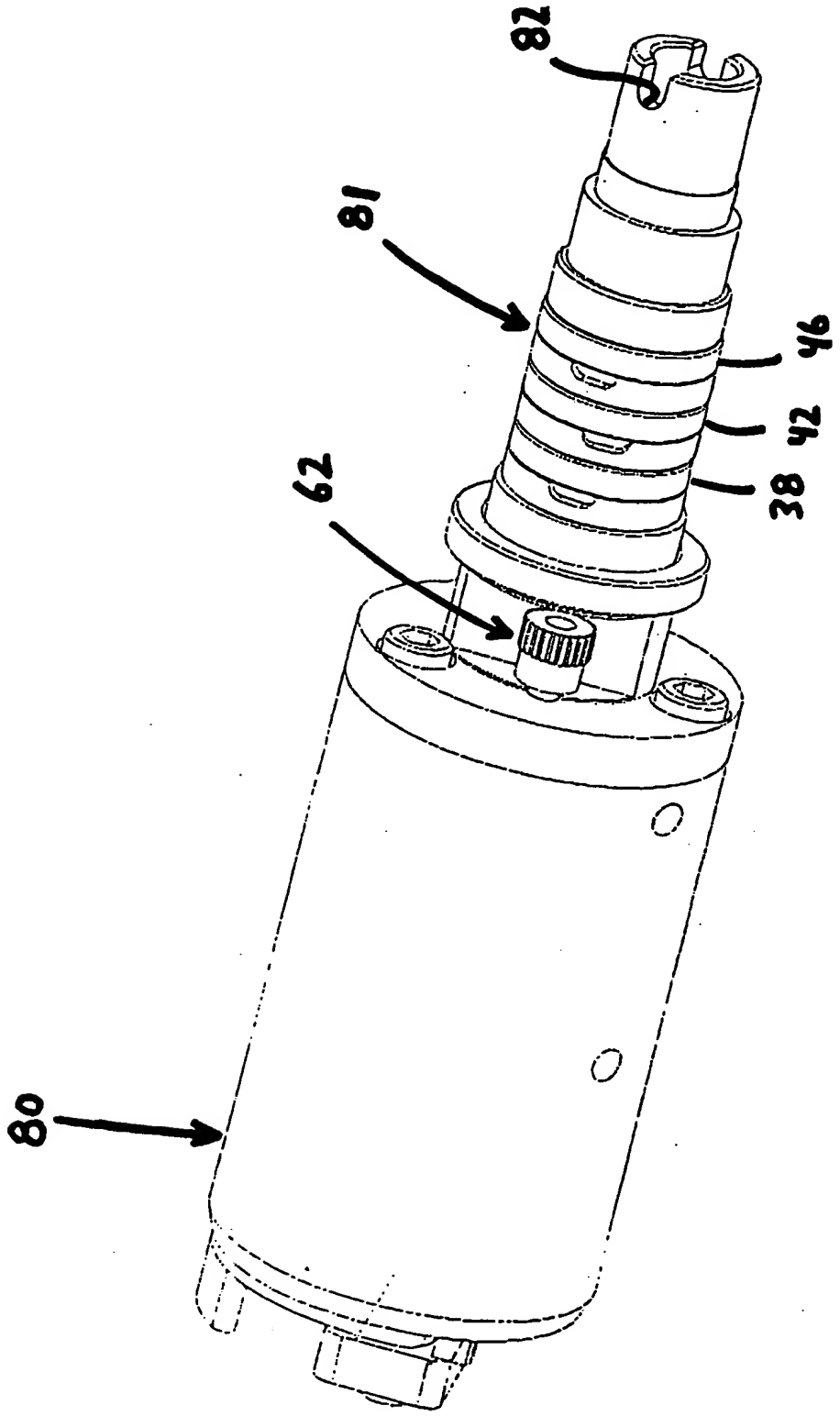

FIG. 4A

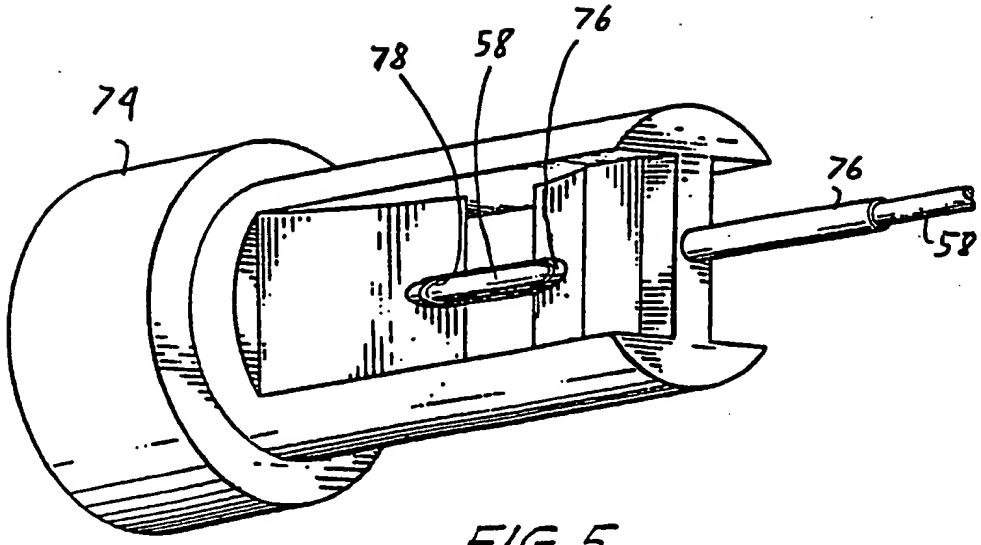

FIG. 5

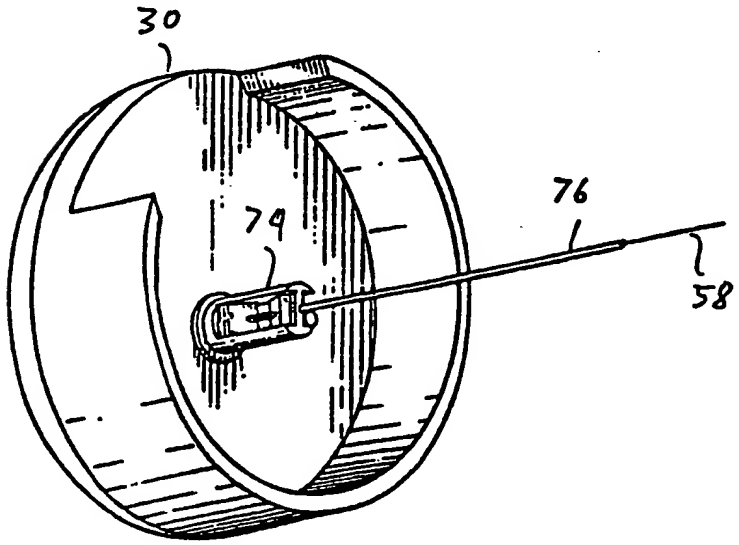

FIG. 6

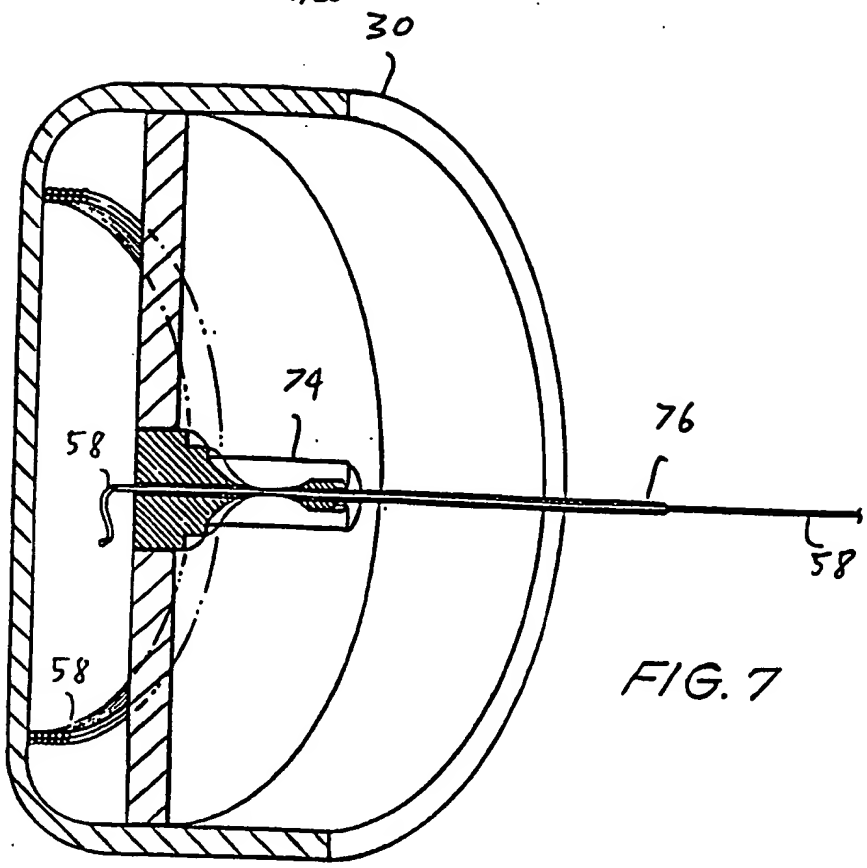

FIG. 7

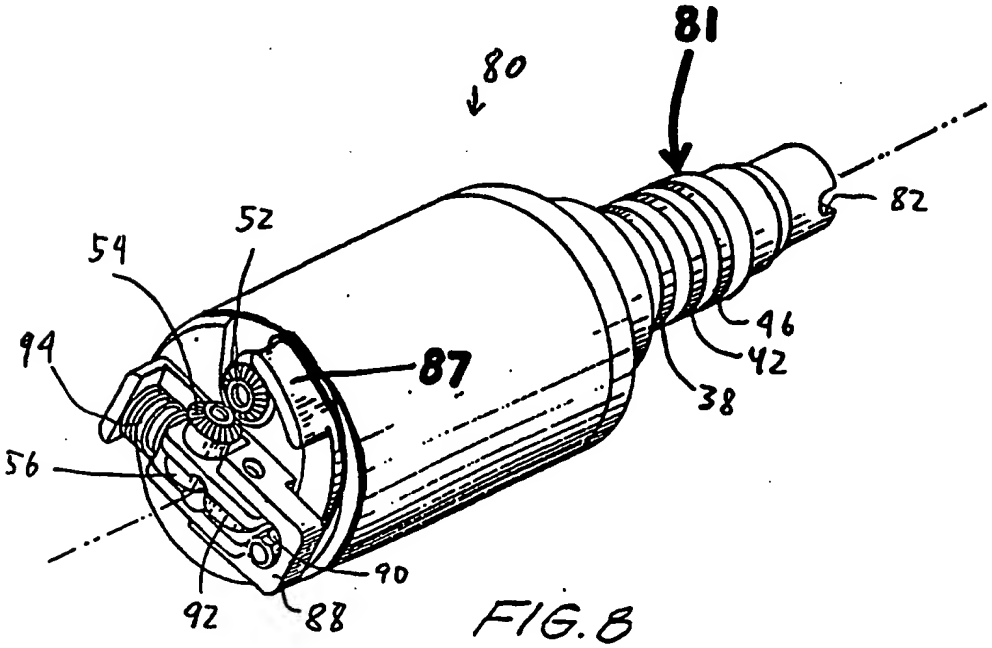

FIG. 8

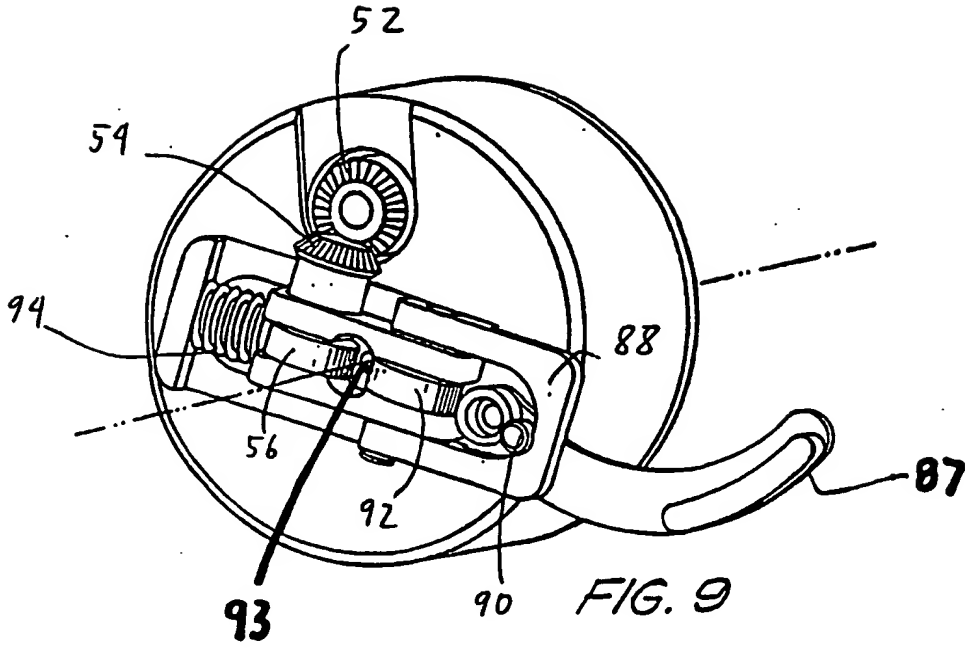

FIG. 9

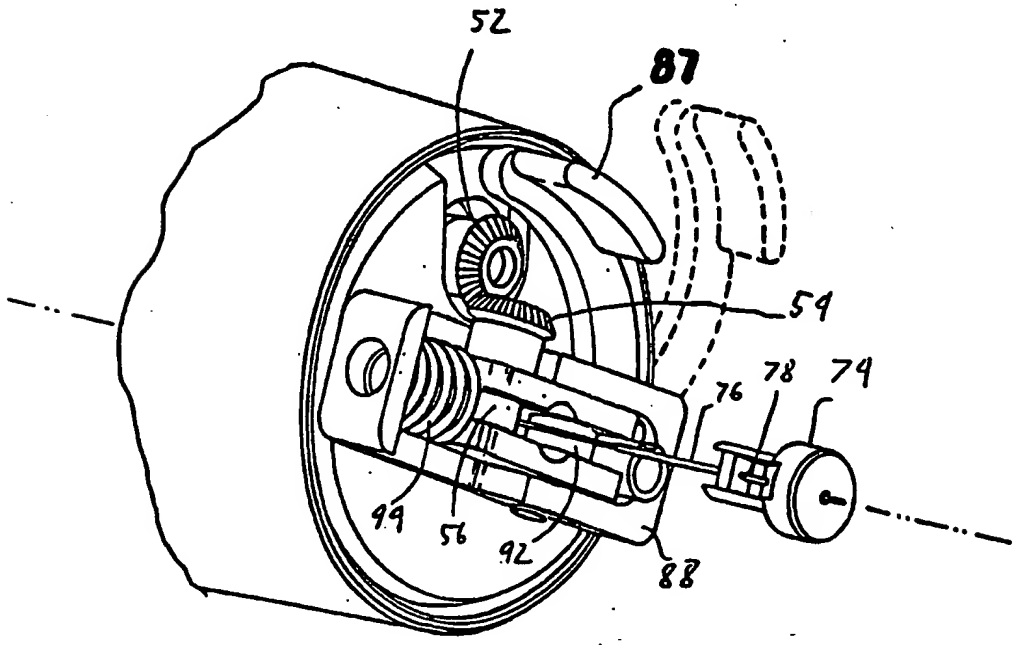

FIG. 10

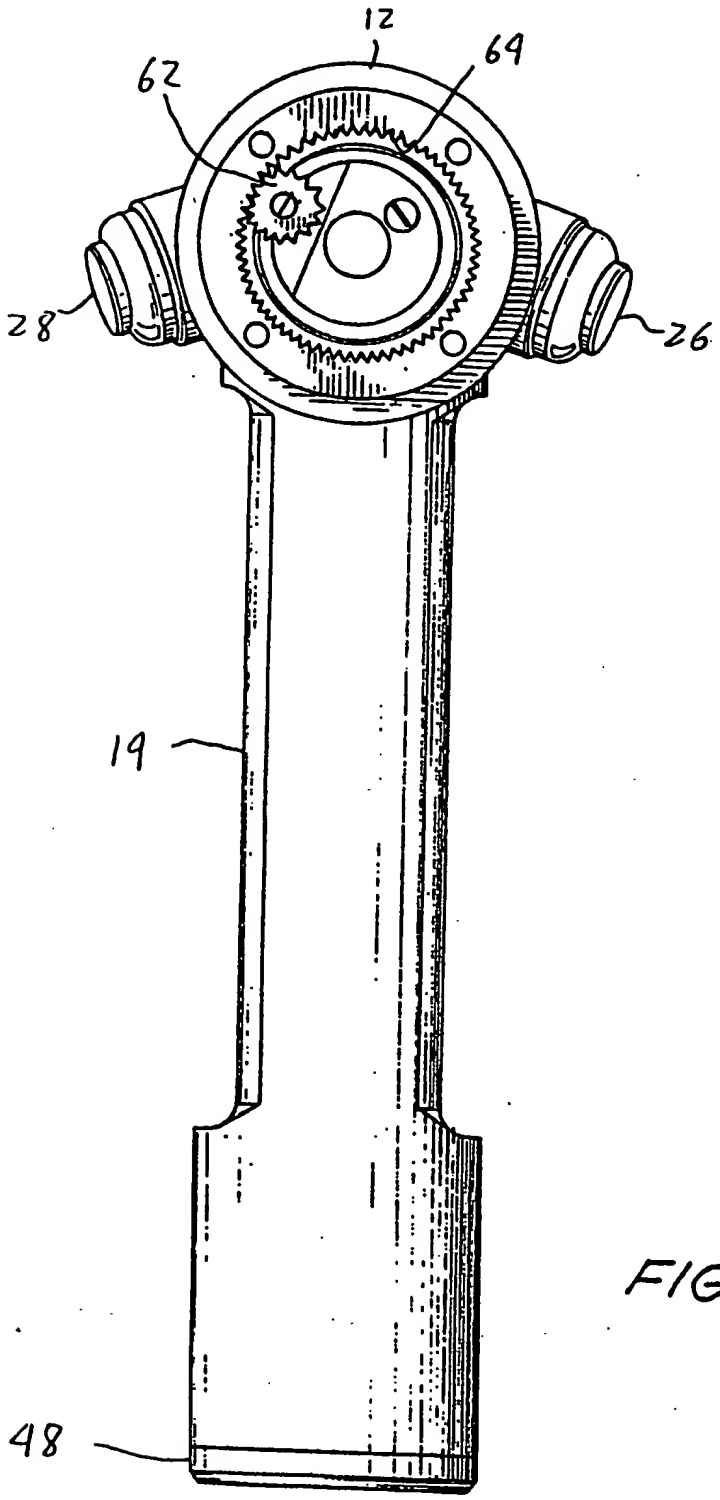

FIG. 11

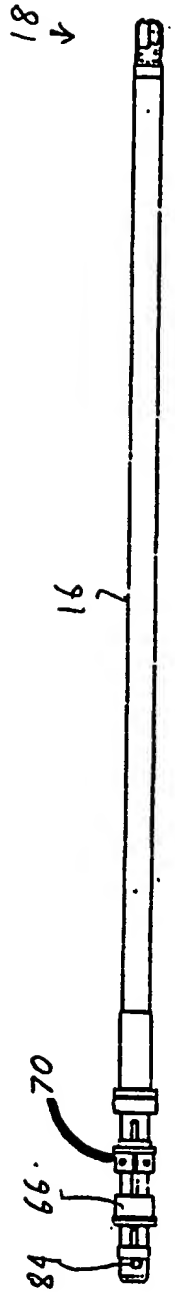

FIG. 12

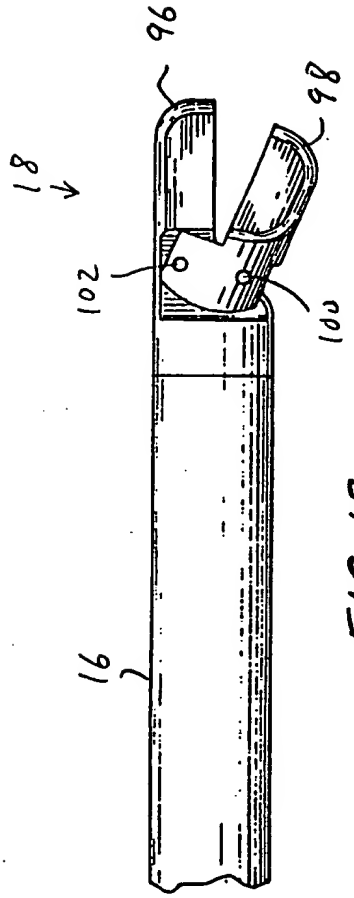

FIG. 13

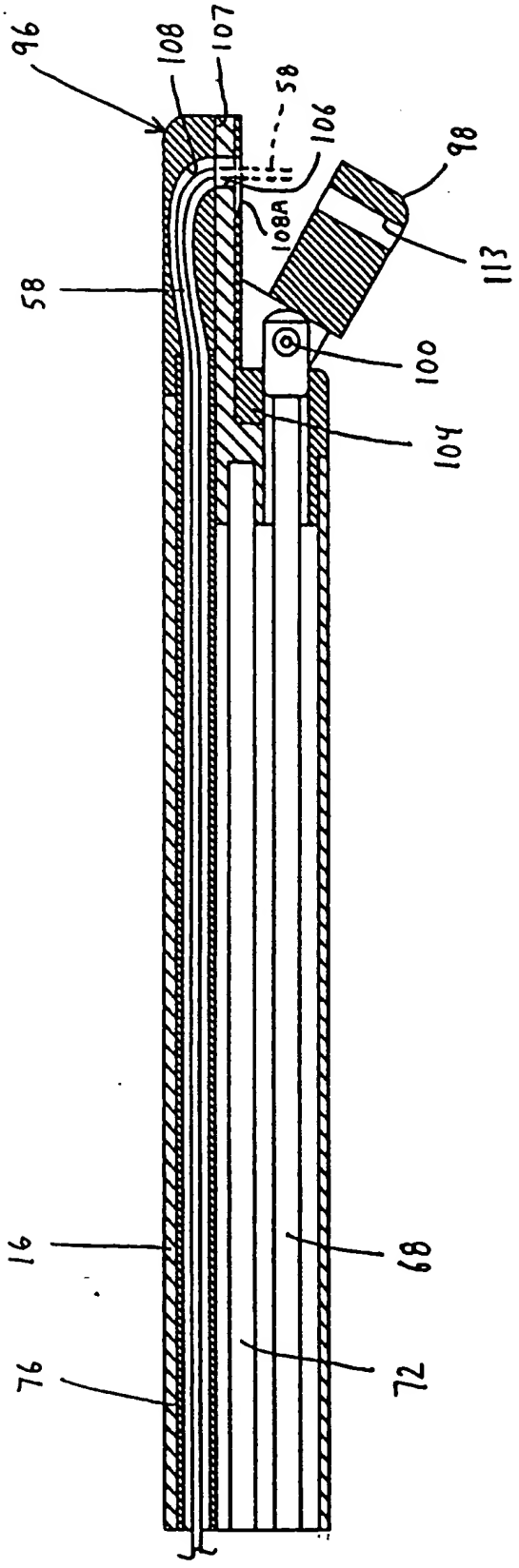

FIG. 14

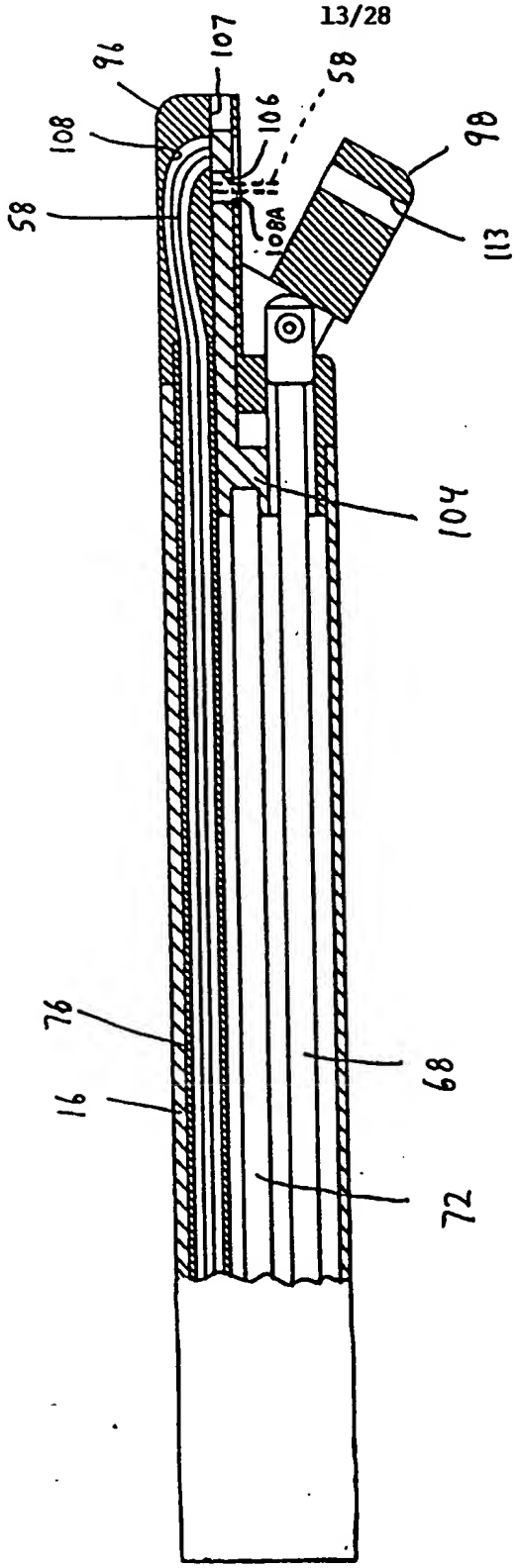

FIG. 15

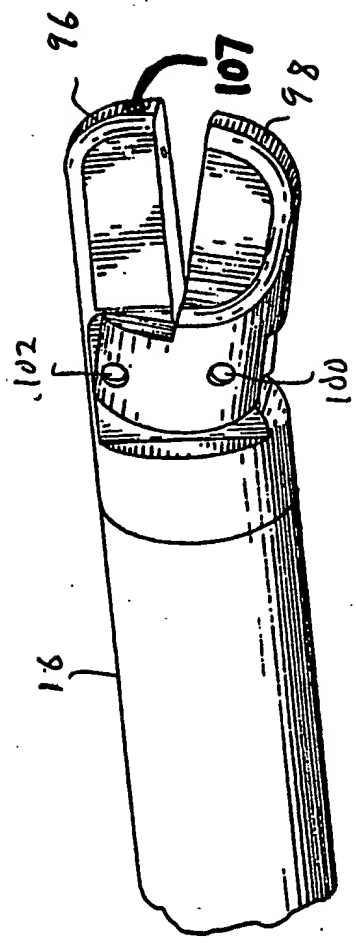

FIG. 16

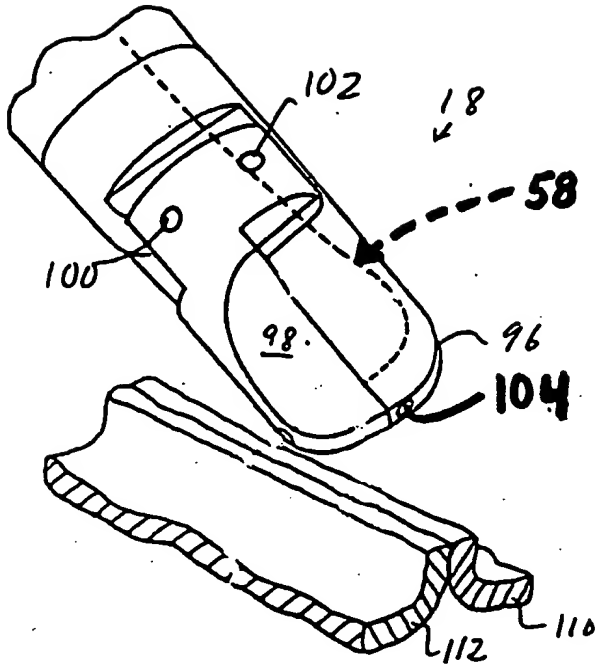

FIG. 17A

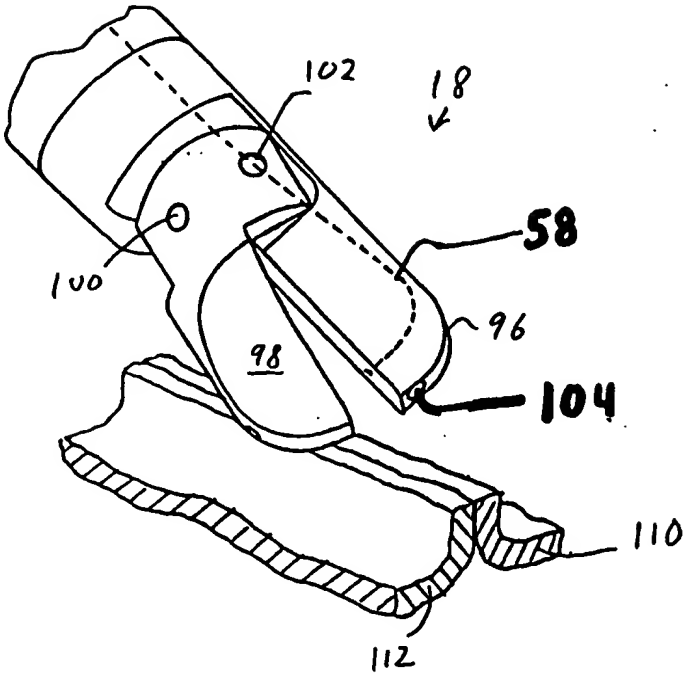

FIG. 17B

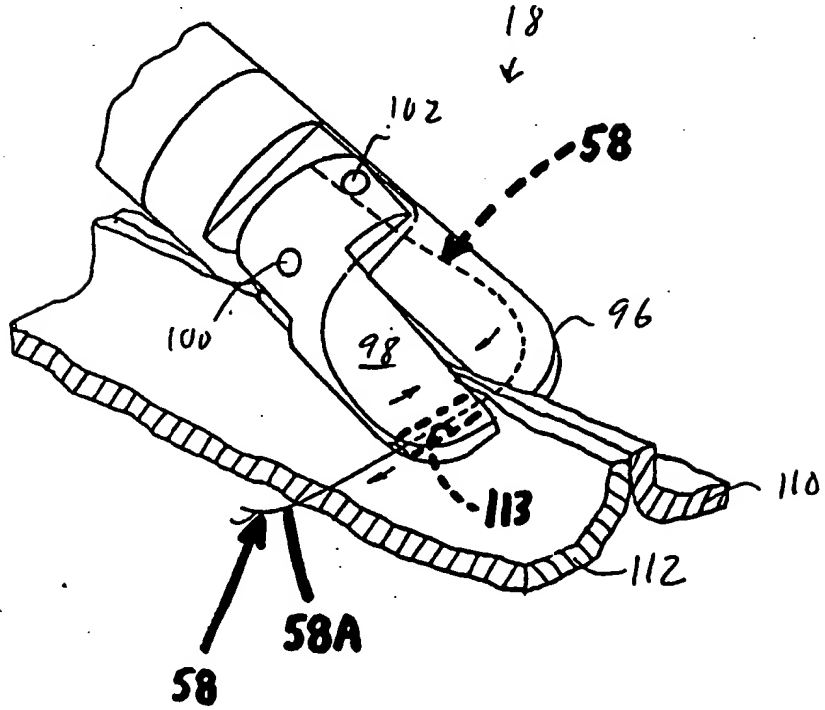

FIG. 17C

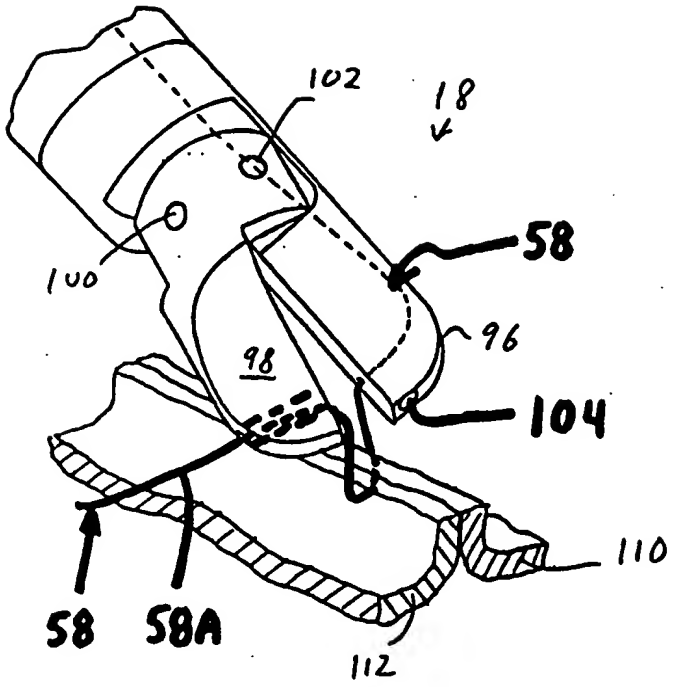

FIG. 17D

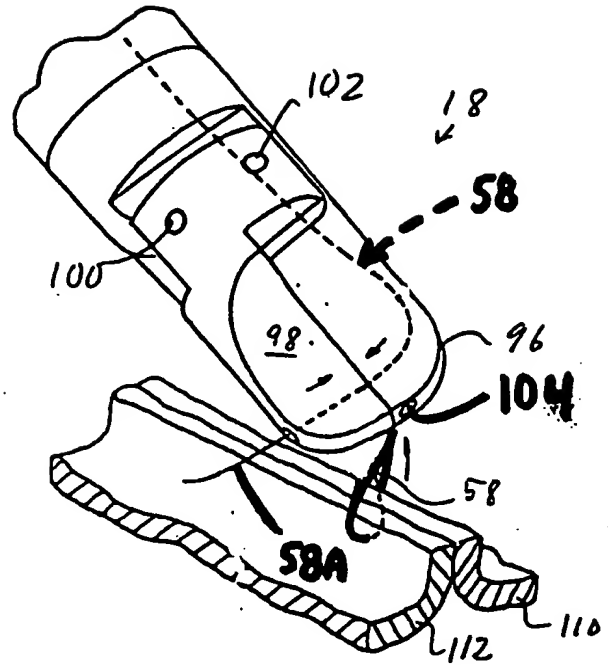

FIG. 17E

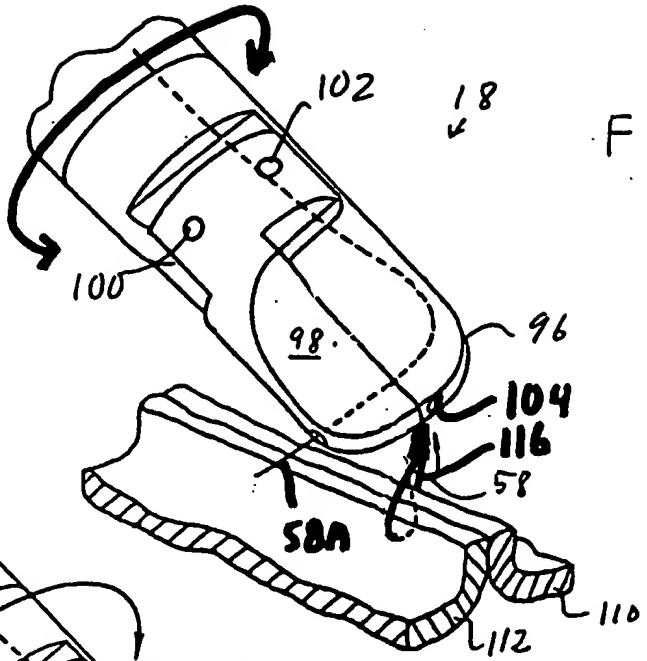

FIG. 17F

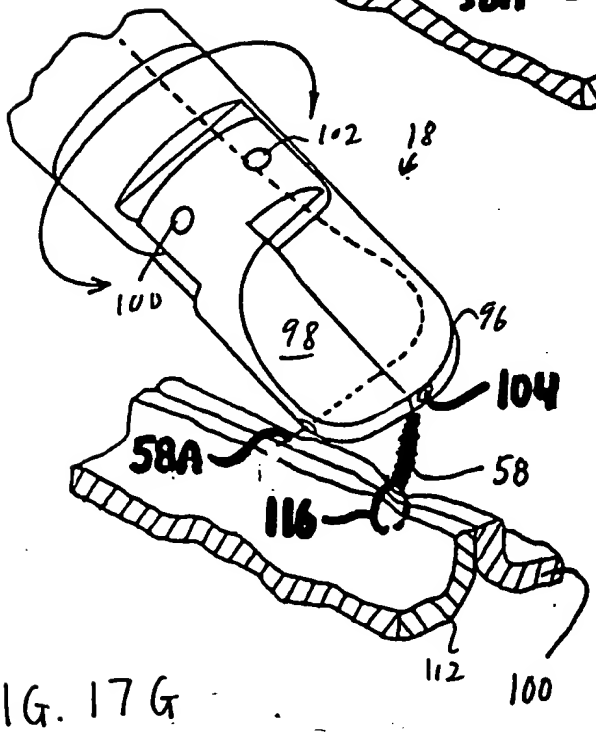

FIG. 17G

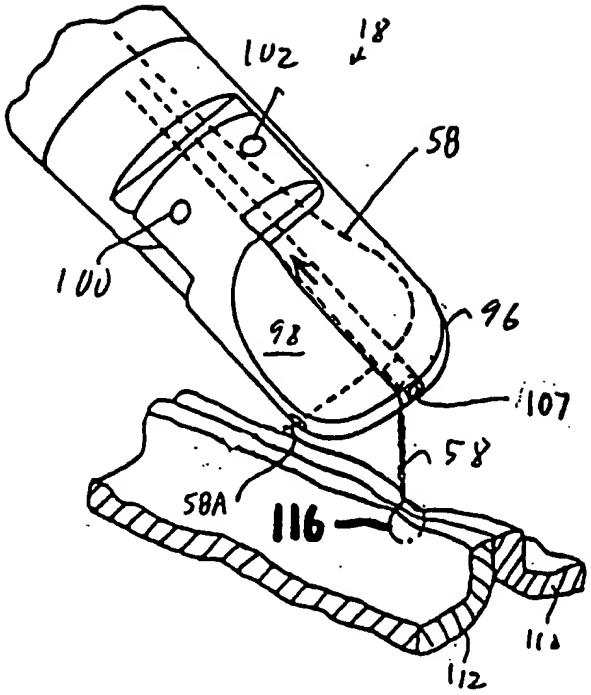

FIG. 17H

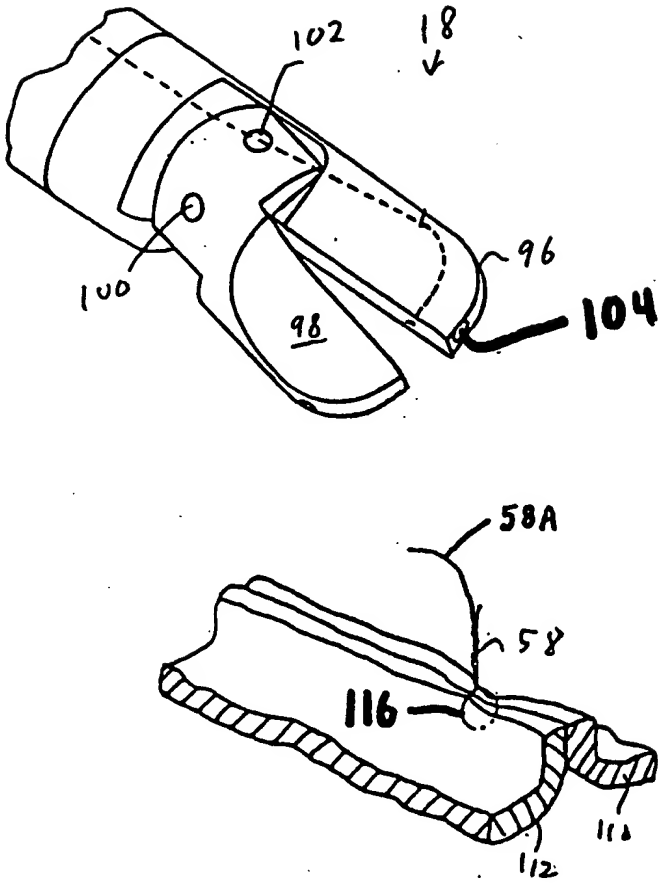

FIG. 17I

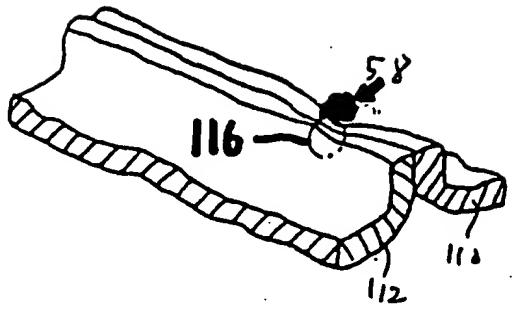

FIG. 17J

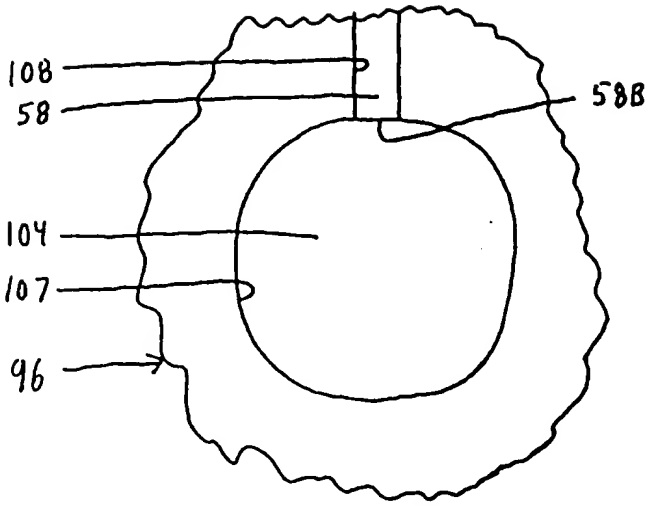

FIG. 18

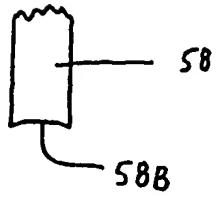

FIG. 19

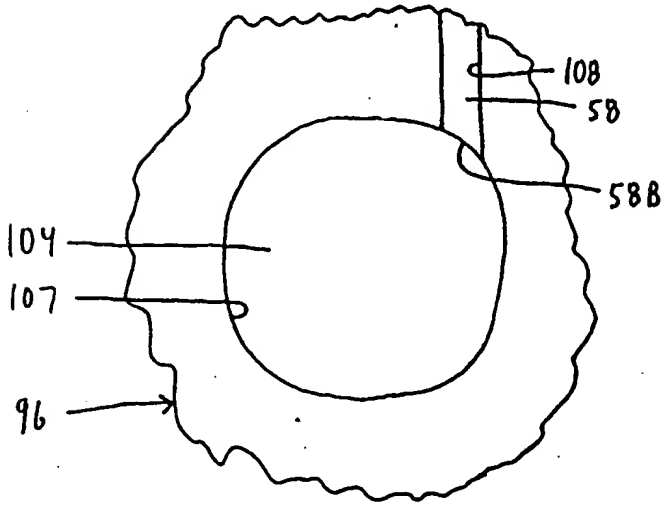

FIG. 20

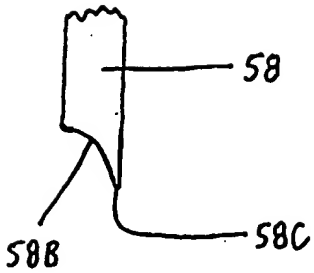

FIG. 21

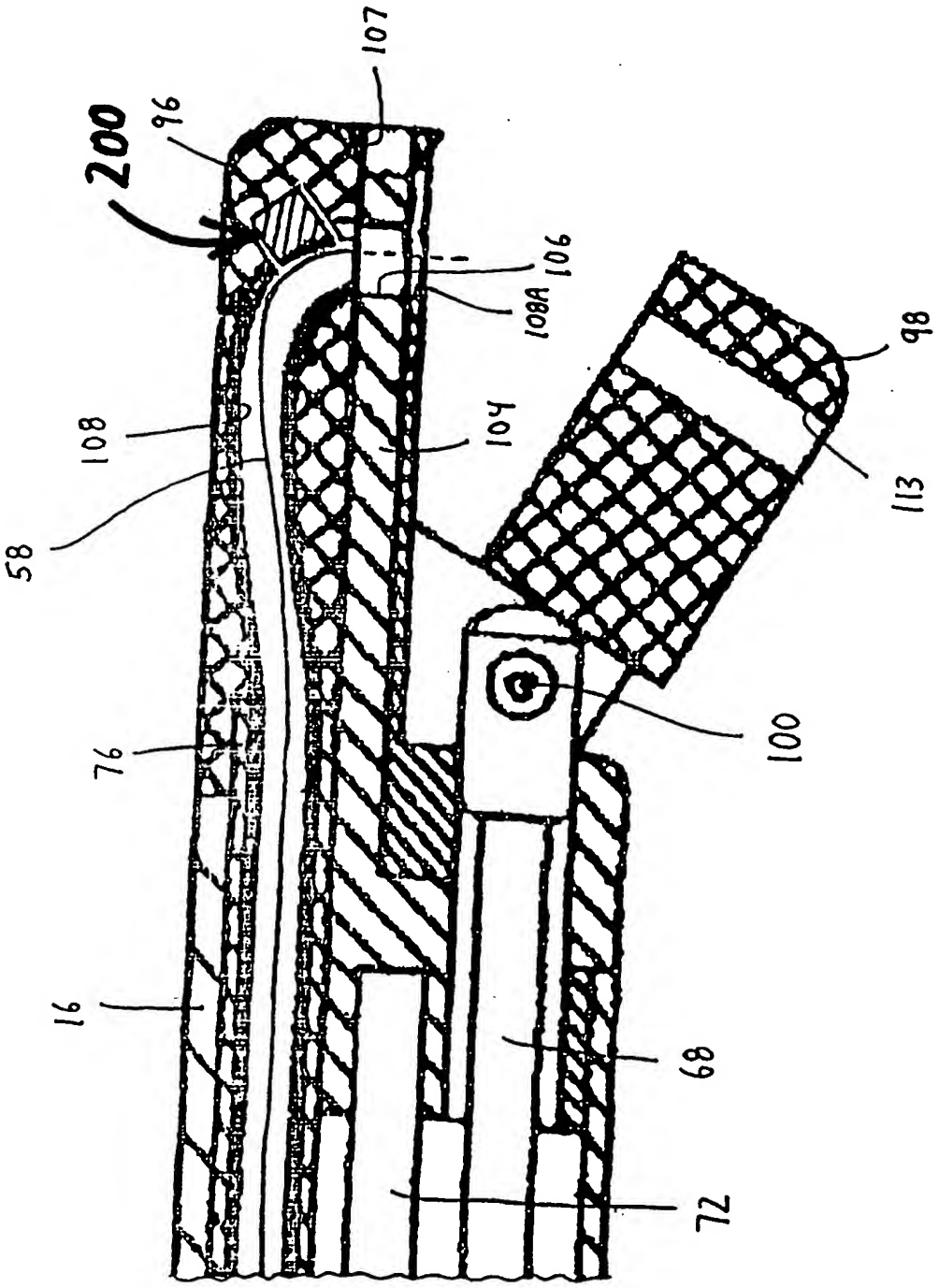

FIG. 22

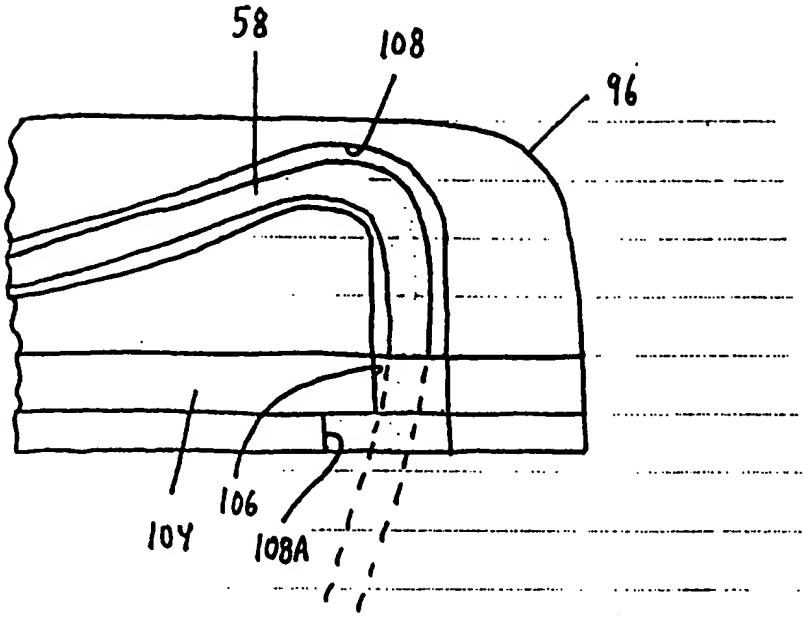

FIG. 23A

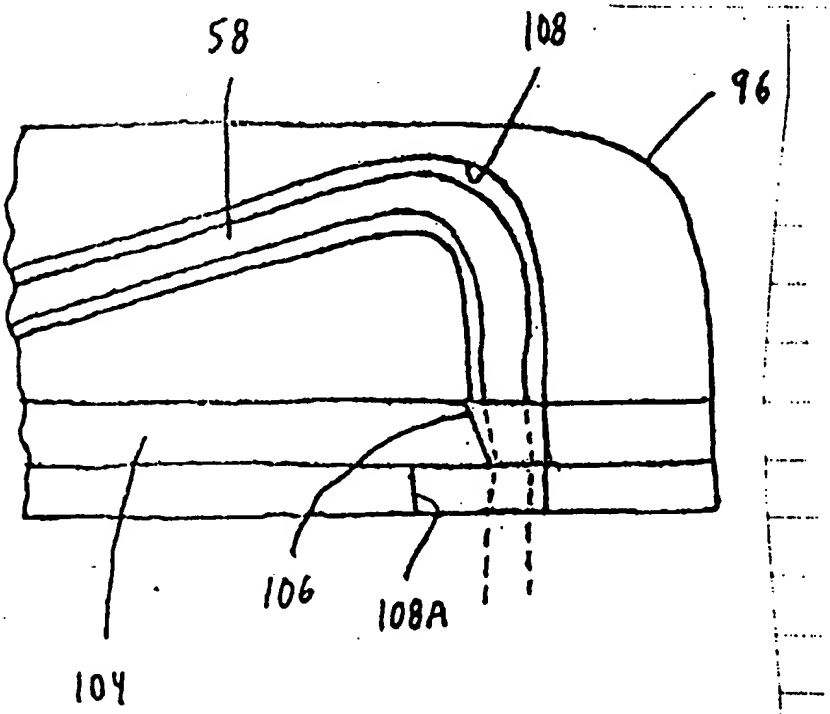

FIG. 23B

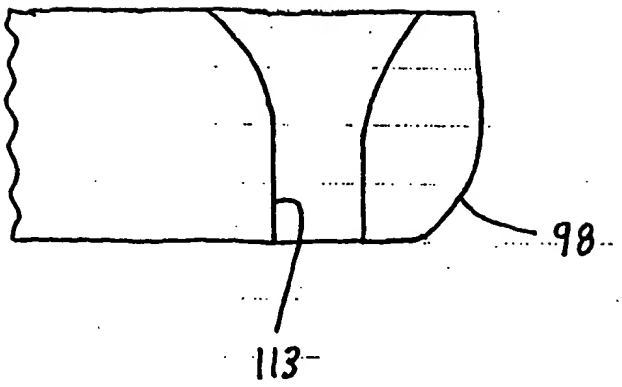

FIG. 23C

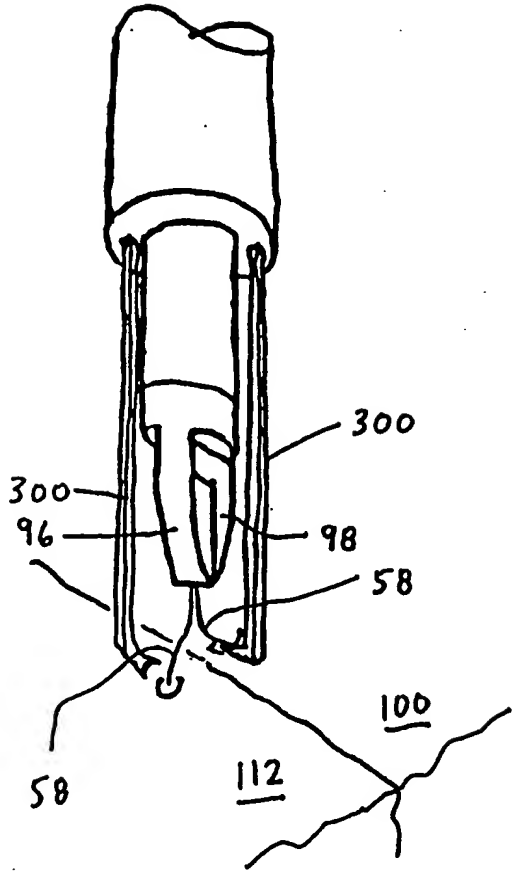

FIG. 24

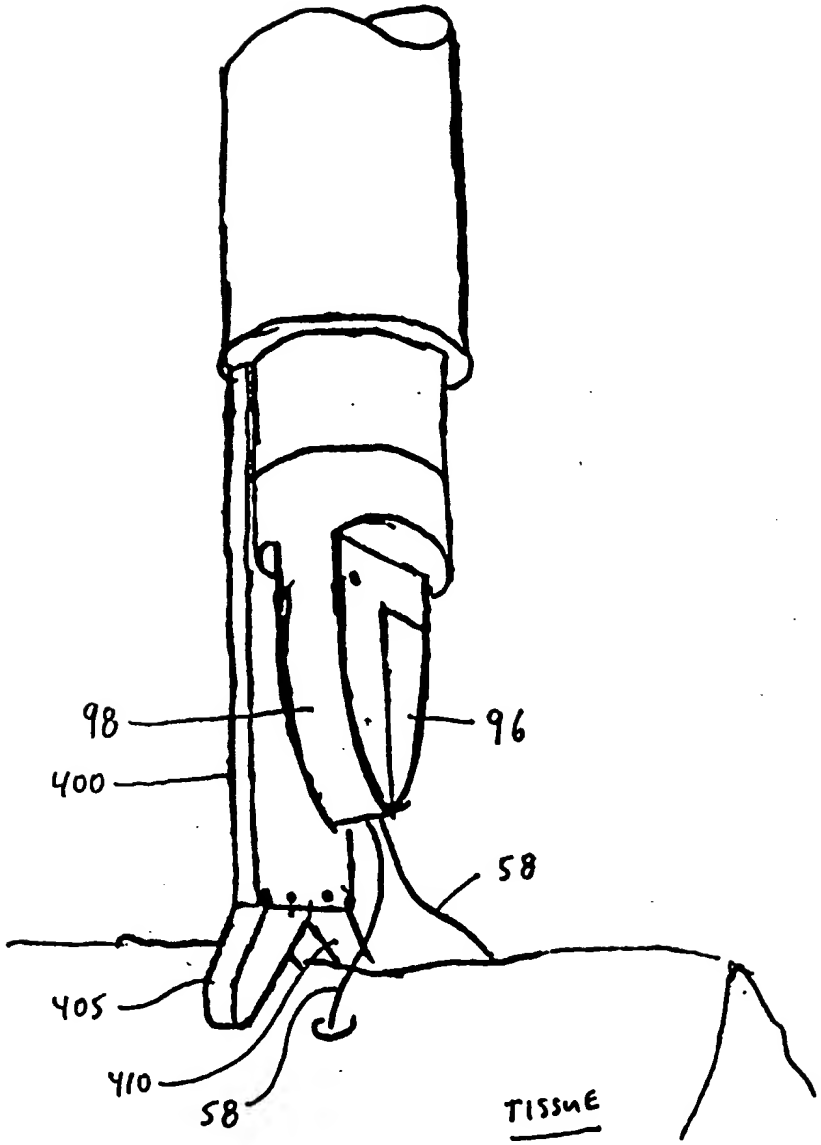

FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/19491

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04
US CL :606/139, 148

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 144, 147, 148

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,814,054 A (KORTENBACH et al.) 29 September 1998, entire document.	1-51

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 07 NOVEMBER 1999	Date of mailing of the international search report 09 NOV 1999
Name and mailing address of the ISA US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238

Form PCT ISA/210 (second sheet)(July 1992)*